Assessing the value of the BSUG database for understanding variations in outcomes of surgery for Stress Urinary Incontinence.

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By

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Abstract

Introduction: Stress urinary incontinence (SUI) is a common, bothersome condition in women, that can be treated by retropubic mesh tapes (RPT), periurethral bulking agents (PUB), autologous fascial sling (AFS) or colposuspension. The British Society of Urogynaecology (BSUG) hosts a surgical database where members record patient and surgical characteristics, outcomes, and complications related to SUI surgery. Data within the database has the potential to demonstrate real life outcomes of surgery, including patient reported outcomes and complications, and to explore the relationship of different characteristics on outcomes to help informed consent and decision making. Variable clinician engagement means the database needs review for ongoing utility.

Methods: A pilot study was undertaken to determine outcomes and complication rates of RPT (n=18763) and PUB (n=1386) and how these varied with the characteristics recorded on the BSUG database: age, BMI, pelvic floor muscle training (PFMT), urodynamic diagnosis (UDS) and grade of operator as isolated variables. Outcomes studied were patient reported global impression or improvement (PGII), cured/improved SUI, new overactive bladder symptoms (OAB), return to hospital and bladder injury. Following the government enforced pause in vaginal mesh products, the analysis was expanded to include an updated dataset, of RPT (n=24923), PUB (n=4740), AFS (n=538) and colposuspension (n=1700), from 2008 to 2019. Multivariable logistic regression was used to compare outcomes between the 4 procedures and a second multivariable model used to assess the effect of the patient characteristics above on outcomes for each procedure. Missing data was variable but significant (3-45%) for some common variables and multiple imputation was employed in the multivariable analysis to address this. A BSUG and International Urogynaecology (IUGA) questionnaire assessed clinician views on the database.

Results: RPT, AFS and colposuspension have high success rates for PGII (91%, 89%, 87%) and SUI (all 96.7%) with PUB having significantly lower odds of positive PGII (56.5%) (OR 0.13; 95% CI: 0.09,0.17; p<0.001) and cure/improvement of SUI (74.1%) (OR 0.10; 95% CI: 0.06,0.14 ; p<0.001) compared to RPT. PUB benefit from significantly lower odds of new OAB symptoms developing (OR 0.20; 95% CI: 0.05, 0.84; p=.028) and significantly lower odds of return to hospital for PUB (OR 0.32; 95% CI: 0.19,0.53; p<0.001) compared to RPT. AFS have higher odds of return to hospital (OR 2.42; 95% CI: 1.07,5,45; p=0.033) compared to RPT.

Bladder perforation rate was 3.6% for RPT, 3.4% for AFS and 3.3% for colposuspension and significantly lower in PUB at 0.1% (OR 0.03; 95% CI: 0.00,0.19; p<0.001). Bladder perforation rates following RPT varied across centres due to higher rates with non-consultant grade surgeons (OR 3.88; 95% CI: 2.99, 5.05; p <0.001).

The odds of a positive PGII for RPT, decreased with increased age (OR 0.83; 95% CI: 0.77,0.90; p<0.001), increased BMI (OR 0.95; 95% CI: 0.93,0.97; p<0.001), pre-operative urodynamic diagnosis that included overactivity (OR 0.51; 95% CI: 0.41,0.64; p<0.001) and intra-operative bladder injury (OR 0.57; 95% CI: 0.37,0.89; P=0.012).

Discussion

Success and complication rates found, provide real life data which can assist with counselling. Data on return to hospital is minimally reported in the literature.

Significant weaknesses with the BSUG database were identified in design, data input and validation and generalisability thus limiting its future use. It remains a useful tool for individual audit and national reports for clinicians that enter data. Further development with input from all stakeholders, including patients, could facilitate wider use in clinical practice and a resource for future research including prognostic data.

Publications related to this thesis to date

Peer review Journal articles

- **Fiona Bach** and Philip Toozs-Hobson. An analysis of 1386 periurethral bulking procedures with comparison to 18,763 retropubic tapes. Post Reproductive Health. Volume 26, Issue 2
- **Fiona Bach**, Simon Hill, Philip Toozs-Hobson. The effect of body mass index on retropubic midurethral slings. Am J Obstet Gynecol. 2018 Dec 18. pii: S0002-9378(18)32228-2. doi: 10.1016/j.ajog.2018.12.018.
- **Fiona Bach**, Philip Toozs-Hobson. What can we learn from large data sets? An analysis of 19,000 retropubic tapes. Int Urogynecol J DOI 10.1007/s00192-016-3162-x.
- Writing group of the International Urogynaecological Association - Philip Toozs-Hobson, Javier Pizarro-Berdichevsky, Vivian Sung and **Fiona Bach**. IUGA report on reporting urodynamics in women. Int Urogynecol J (2021). https://doi.org/10.1007/s00192-021-04742-w
- P Toozs-Hobson, **Fiona Bach**, J Purnell. Making best use of clinical datasets: with examples from urogynaecology. The Obstetrician and Gynaecologist (TOG). (Accepted for publication.)
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Oral presentations

Trends, Outcomes and Multivariable Analysis of Continence Surgery from the BSUG Database. **Fiona Bach**, Philip Toozs-Hobson.

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What can we Learn from Large Data sets? When we use Bulking Procedures and Comparison to Mid-Urethral Slings (MUS).

IUGA Vancouver, 2017. **Fiona Bach**, P Toozs-Hobson, J Duckett

Value Based Healthcare: The effect of Body Mass Index (BMI) on Success and Complications of 12,000 Midurethral slings (MUS).

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See appendix 1

Abbreviations

AFS	Autologous Fascial sling
ALPP	Abdominal leak point pressure
AR	Anterior repair
BAUS	British Association of Urological Surgeons
BMI	Body Mass index
BSUG	British Society of Urogynaecology
CI	Confidence interval
COMET	Core Outcome Measures in Effectiveness Trials
COS	Core outcome set
CPR	Patient Identifier in DUGAbase
CPRD	Clinical Practice Research Datalink
CROWN	Core Outcomes in Women's Health
CST	Cough stress test
DO	Detrusor overactivity
EMB	Evidence Based Medicine
EMR	Electronic medical records
ePAQ	Electronic Personal Assessment Questionnaire
FTSTA	Fixed Term Specialty Training Appointment
GA	General anaesthetic
GDPR	General Data Protection Regulation
GIRFT	Getting it right first time
HCT	Historical controls trials
HES	Department of Health Hospital Episode Statistics

HQIP	Healthcare Quality Improvement Partnership
ICHOM	International consortium of health outcomes measures
ICIQ	International consultation on incontinence questionnaire
ICIQ-UI short form	ICIQ for urinary incontinence
ICIQ-VS	ICIQ vaginal symptoms
ICIQ-LUTS	ICIQ Urinary symptoms quality of life (Kings health questionnaire)
ICIQ-OAB	ICIQ overactive bladder
ICS	International Continence Society
IEF	Incontinence episode frequency
IIQ	Incontinence impact question
IP	Intellectual property
ISD	Intrinsic sphincter deficiency
IUGA	The International Urogynaecological Association
MBRRACE-UK	Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK
MDT	Multidisciplinary Team
MESA	Medical Epidemiologic and Social Aspects of Ageing
MHRA	Medicine and Healthcare products Regulatory Agency
MMK	Marshall Marchetti Krantz procedure
MUCP	Maximum urethral closure pressure
MUS	Mid urethral sling – to incorporate both RPT and TOT
NCAP	National Cardiac Audit Programme
NCIP	National Consultant Information Programme

NCRAS	National Cancer Registration and Analysis Service
NEJM	The New England Journal of Medicine
NHS	National Health Service
NICE	The National Institute for Health and Care Excellence
NICOR	National Institute for Cardiovascular Outcomes Research
NIHR	National Institute for Health Research
NJR	National Joint Registry
OAB	Overactive bladder symptoms
ONS	Office for National Statistics
OR	Odds ratio
PFMT	Pelvic floor muscle training
PGII	Patient-reported global impression of improvement of incontinence - VMB - Very much better - MB - Much better - LB - A little better - NC - No change - LW - A little worse - MW - Much worse - VMW - Very much worse
PIAG	Patient information advisory group
PM	Consultant responsible for setting up the BSUG database
POPQ	Pelvic organ prolapse quantification
PR	Posterior repair
PREM	Patient reported experience measures

PROBAST	Prediction model Risk Of Bias Assessment Tool
PROM	Patient Reported Outcome Measures
PUB	Periurethral bulking agent
PVR	Post void residual
QOL	Quality of life
RCOG	Royal College of Obstetricians and Gynaecologists
RCT	Randomised control trial
RdTH	Readmitted to hospital
ROB	Risk of bias
RPT	Retropubic mesh tape
RTH	Return to hospital
RTT	Return to theatre
SCP	Sacrocolpopexy
SCTS	Society for Cardiothoracic Surgery
SD	Standard deviation
SHP	Sacrohysteropexy
SIDS	Sudden Infant Death Syndrome (SIDS)
SISTEr	The Stress Incontinence Surgical Treatment Efficacy Trial
SOAS	Sling on a string
SOP	Standard operating procedure
SPA	Supporting Professional Activities
SPIRIT	Standard Protocol Items-Recommendations for Interventional Trials
SSF	Sacrospinous fixation
SST	Subspecialty trainee

ST	Specialist trainee
STAR	Socio-Technical Allocation of Resources model
SUI	Stress urinary incontinence
TOG	The Obstetrician and Gynaecologist: Journal of RCOG
TOT	Transobturator mesh tape
TVT	Tension Free vaginal Tape
UGSA	Urogynaecology Society of Australasia
UKCS	United Kingdom Continence Society
UDI	Urogenital distress inventory
UDS	Urodynamic studies
USI	Urodynamic stress incontinence
VBHC	Value based health care
VD	Voiding dysfunction
VH	Vaginal hysterectomy
VLPP	Valsalva leak point pressure

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Chapter 1

Background of thesis

Urinary incontinence is common, reported as affecting 40% of women in a population-based cross-sectional postal survey of female patients from a medical centre in the United Kingdom in 2014. The women questioned in the survey reported being embarrassed (16%), unhappy (12%) and very unhappy (4%) [4]. The impact on quality of life (QOL) can be vast and lead to loss of social life, loss of earnings and decreased well-being.

Stress urinary incontinence (SUI) is described as involuntary loss of urine with increased intra-abdominal pressure [5]. This can be seen in isolation or as mixed urinary incontinence when SUI is coupled with the symptoms of overactive bladder (OAB) defined as urinary urgency, frequency and nocturia, with or without urgency urinary incontinence [6]. Management options for SUI are varied and have undergone significant changes in both technique, as well as physician and patient preference over the past 100 years. Conservative measures [7] include fluid management [8], weight loss , reducing chronic cough [9], pelvic floor muscle training (PFMT) [10] and vaginal pessary [11], or pharmacological treatment can be considered if no other treatments are suitable [12]. Surgical options include periurethral bulking agents (PUB) [13], autologous fascial sling (AFS) [14], colposuspension [15], mid urethral mesh tape [16] and artificial urethral sphincter [17]. Surgery may fail and some women do not desire treatment. OAB is treated by similar conservative measures of fluid management and weight loss with bladder retraining and pharmacological treatment [12]. If these initial measures do not work then other treatments can be considered such as botulinum toxin A [18] (Botox®) to the detrusor muscle of the bladder, percutaneous tibial nerve

stimulation (PTNS) [19] or sacral nerve stimulation (SNS) [20]. If treatment fails or is declined, containment products, including a urinary catheter, may be used [12].

It is currently not clear which management strategy is the best for each patient [21]. Thus, there is the need for robust short and long-term follow up of urinary incontinence treatments to help determine the “right” treatment for the individual in terms of patient choice, suitability and efficacy depending on the characteristics of that patient. The British Society of Urogynaecology (BSUG) is a national society dedicated to urogynaecology that is the branch of medicine that manages urinary incontinence and vaginal prolapse in women. The society has a surgical database known as the BSUG database where gynaecologists, who are members of BSUG, can record incontinence and prolapse surgery cases. The type of surgery, patient characteristics, operating practitioner, and intra-operative complications are recorded on the day of surgery. Patient reported outcomes and post-operative complications are entered following patient review. This was initially set up as personal audit tool for surgeons and has now developed into a large national database. Previously, there had been limited formal analysis of data from the database due to conflicts in the society regarding data ownership and journal article authorship. This has now been resolved and an annual report of numbers of surgical procedures with basic outcomes is published on the BSUG website [22]. Due to the high numbers of cases entered onto the database these is the potential to use it for further, more in-depth, analysis to understand what factors may influence outcomes for stress urinary incontinence surgery and whether a prognostic model could be established to assist in counselling. The strengths, limitations and potential biases of the data must be understood to be able to interpret the results and to ensure validity before using them to influence clinical management.

Diagnosis and management of Stress Urinary Incontinence

Definition

Stress urinary incontinence can describe a symptom, a sign, an investigation result, or a diagnosis as per the International Continence Society (ICS) (Table 1).

Symptom	***SUI***	Complaint of involuntary loss of urine on effort or physical exertion including sporting activities, or on sneezing or coughing. [5]
Sign	***SUI (clinical stress leakage)***	Observation of involuntary leakage from the urethral orifice synchronous with effort or physical exertion, or on sneezing or coughing. [5]
	SUI on prolapse reduction (occult or latent stress incontinence)	Stress incontinence only observed after reduction of co-existent pelvic organ prolapse. [23-25]
Investigation result	***Urodynamic stress incontinence (USI)***	Involuntary leakage of urine during filing cystometry, associated with increased intra-abdominal pressure, in the absence of a detrusor contraction. [5]
Diagnosis	***Urodynamic stress incontinence (USI)***	The diagnosis by symptom, sign, and urodynamic investigations involves the finding of involuntary leakage during filling cystometry, associated with increased intra-abdominal pressure, in the absence of detrusor contractions [23-25]

Table 1: Definitions of stress urinary incontinence as per the International Continence Society

The impact of symptoms on individual women is variable, dependent on the amount and frequency of urinary leakage and ultimately the effect it has on QOL.

Assessment

The initial assessment of urinary incontinence is multifaceted, including a history taken by a health care professional such as a general practitioner, physiotherapist, specialist nurse or hospital doctor, most commonly a gynaecologist, urogynaecologist, urologist, or elderly care physician. Global, abdominal and vaginal examinations are performed, and SUI may be demonstrated by simple measures to increase the intra-abdominal pressure such as a cough or Valsalva manoeuvre. Urinary infection is excluded using a dipstick test and post void residual volume can be assessed using a bladder scanner. A bladder diary is recommended as a basic investigation by The National Institute for Health and Care Excellence (NICE) [12]. The NICE guideline recommends using a validated questionnaire specific to urinary incontinence and a quality-of-life questionnaire but does not specify which one. These can be used to assess the severity and impact of symptoms at initial presentation and used to measure improvement post intervention [26].

More advanced assessment of urinary incontinence involves urodynamic studies (UDS), which are used to further clarify the type of incontinence by assessing bladder filling, storage and emptying. The test is performed using a catheter to fill the bladder. Pressure in the bladder and abdomen are measured during filling, manoeuvres such as coughing, and voiding to give the diagnosis.

A longstanding teaching that “the bladder is an unreliable witness” [27] has meant that UDS have been routinely performed before surgery for SUI. It has been shown that lower urinary tract symptoms do not always correlate with the urodynamic diagnosis [28] with the theoretical anxiety that detrusor overactivity (DO), can mimic the

symptoms of SUI or co-exist, and in these cases surgery may lead to worsening OAB symptoms. However, there remains debate regarding the utility of UDS prior to incontinence surgery. VALUE and VUSIS trials, published between 2012 and 2015 [29-32], demonstrated non-inferiority of preoperative office evaluation for women with uncomplicated, demonstrable stress urinary incontinence, compared to urodynamic testing, for outcomes at one year [30, 32]. A 2013 Cochrane review concluded that clinical decision making may be influenced by urodynamic tests but there was not enough evidence to say this translated into improved clinical outcomes [33]. Zimmern et al. illustrated that urodynamic studies increased clinician confidence but did not improve patient outcomes [34]. Detractors would argue that UDS can be a complex investigation and the subtleties are often overlooked, particularly if the clinician interpreting the test is not the clinician performing this test, as there is significant inter and intra-observer differences when urodynamic traces are reviewed over 4 month intervals [35]. United Kingdom NICE Guidance, published in 2019, states that UDS are not required prior to performing a primary retropubic tape (RPT) if stress urinary incontinence or stress-predominant mixed urinary incontinence is diagnosed on history and examination [12].

Management

The management of SUI should be agreed between the patient and the health care professional. Conservative measures should be offered first with surgical management only being pursued if these are not successful [12].

i. Conservative

A patient bladder diary records fluid input and output over 1-3 days, and can be informative to the clinician and patient. This can be used to optimise fluid management

to ensure the patient is drinking the correct amount and type of fluids at appropriate times and is emptying their bladder regularly. Weight loss can help with urinary symptoms [36] aiming for a BMI <30 and this is beneficial for optimising surgical outcomes and safety [37]. A chronic cough worsens SUI symptoms and so this should be managed by optimising the respiratory system and medication review. Supervised pelvic floor muscle training (PFMT) has been shown to reduce symptoms of SUI [38]. Vaginal pessaries designed to improve SUI can also be used [39, 40].

ii. Medical

Although not recommended as a first line treatment, NICE supports the option of Duloxetine (serotonin-norepinephrine reuptake inhibitor) as a licensed treatment of SUI [12]. Vaginal oestrogen may be offered particularly in patients with vaginal atrophy, but systemic oestrogen is associated with worsening SUI symptoms [41].

iii. Surgical

NICE guidelines from 2019 state that women should be offered the choice of RPT, AFS or colposuspension, as surgical options for SUI and recommend using PUB if other options are not acceptable to the patient [12]. In the UK, the NICE decision-making tool has been introduced to aid patients' decision-making skills in conjunction with a clinician [38, 42].

There are many factors that can influence the outcomes of surgery, and these can be broadly divided into patient factors and surgical factors [27-34, 43-49]. Identification of these factors and their impacts allow patients to make a more informed and bespoke choice about management of SUI. Patients may decide to defer intervention whilst

undertaking lifestyle changes in order to modify characteristics that could compromise outcomes and it may assist decision making about which surgery to opt for.

a. Periurethral Bulking Agents

Periurethral bulking was first described in the early 1900's, originally using paraffin and subsequently with a variety of other materials (table 2).

It is a minimally invasive procedure where a substance is injected into the periurethral area, close to the bladder neck, to increase apposition of the urethra to avoid urinary leakage (Figure 1). It is a relatively simple and quick procedure with minimal complications and short recovery time [13].

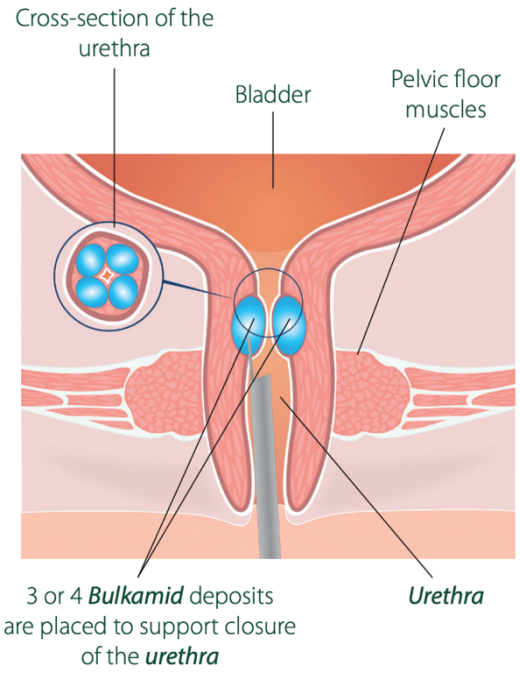


Figure 1: Bulkamid system for periurethral bulking as a treatment for stress urinary incontinence [1]

Historically their indications have been more of a salvage procedure reserved for elderly or medically unfit patients due to their lower risk profile [50].

Date	**Material**
1904	Paraffin *(Meyer)*
1938	Sodium morhuate
1955	Paraffin injected into peritoneum
1963	Sclerosant – Dondren
1973	Polytetrafluoroethylene (Teflon®)
1977	Bovine collagen (Contigen®)

1989	Autologous fat
1992	Silicon particles (Marcoplastique®)
1999	Dextranomer/hyaluronic acid (Zuidex®/Deflux®)
1999	Carbon coated beads (Durasphere®)
2001	Calcium hydroxylapatite (Coaptite®)
2003	Etylene vinyl alcohol (Tegress®)
2006	Polyacrylamide hydrogel (Bulkamid®)

Table 2: Materials that have been used for periurethral bulking with dates of first use

b. Autologous Fascial sling (AFS)

More invasive surgical techniques for female SUI began to develop in 1942, when Aldridge described the fascial sling. Two arms of abdominal fascia above the symphysis pubis were harvested, maintaining the medial attachment, which allowed the lateral portions of the arms to be passed down through the cave of Retzius and sutured suburethrally at the urethrovesical junction [14]. A modification of this technique has been dubbed the 'sling on a string' where a strip of fascia is harvested from the anterior abdominal wall or fascia lata and passed through retropubic tunnels, from a vaginal incision, to support the urethra [51] (Figure 2)

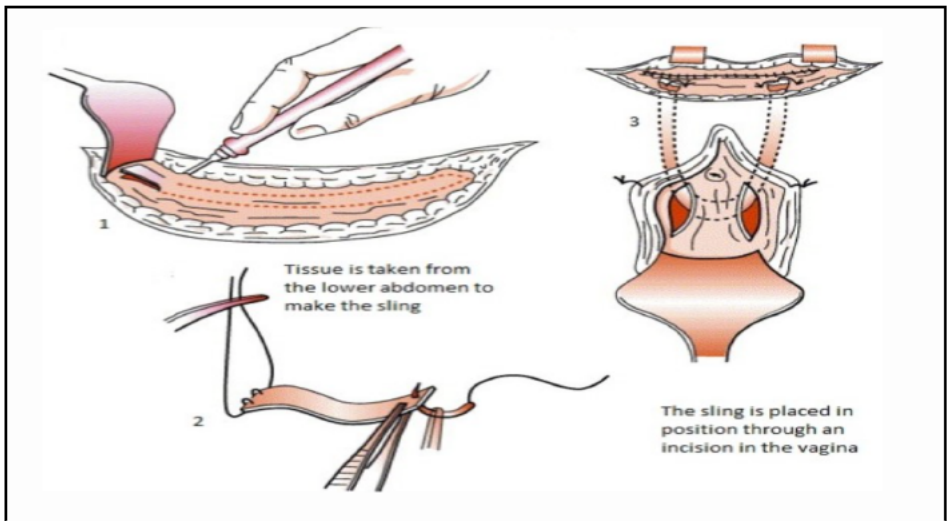


Figure 2: Fascial sling on a string as a treatment for stress urinary incontinence [3]

c. Colposuspension

Colposuspension was described by Burch in 1961 [15] and was popular with gynaecologists through the 1980s and 1990s [3]. An abdominal approach is used to elevate and fixate the paraurethral fascia to Cooper's ligament. It can be performed laparoscopically or as an open procedure (Figure 3 [52]).

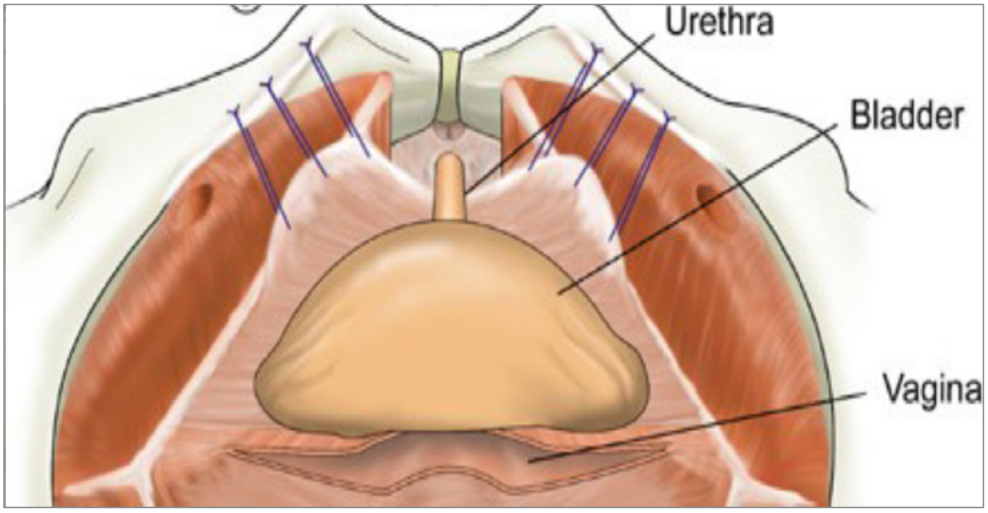


Figure 3: Colposuspension as a treatment for stress urinary incontinence [52]

d. Midurethral Mesh tape

Both the AFS and colposuspension are major surgery and have significant risks with long recovery times, which, for some physicians and patients, are unacceptable for a benign condition. Ulmsten et al first described the mid-urethral mesh tape in the mid-1990s [16, 53] with many different variations subsequently developed with different introducers and materials for the mesh ribbon.

A synthetic mesh is inserted using trochars which enter through a small incision in the vagina and exit the skin just cephalad to the symphysis pubis to position a ribbon of mesh under the mid portion of the urethra to provide support when the intra-abdominal pressure increases (Figure 4).

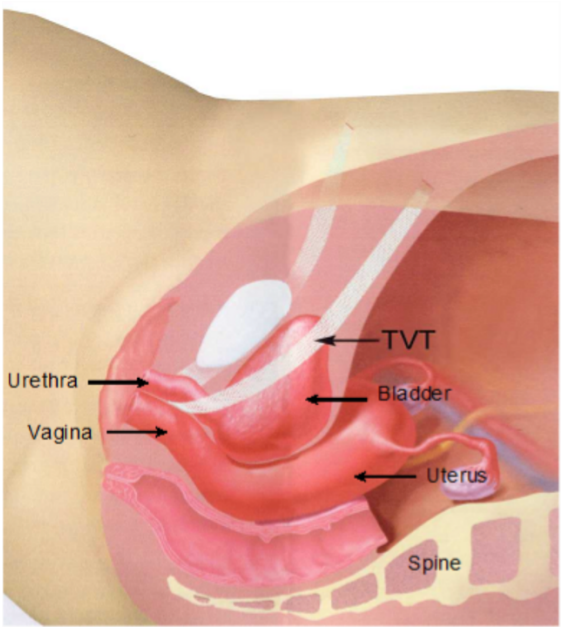


Figure 4: Retropubic Mesh Tape as a treatment of stress urinary incontinence [54]

A second-generation procedure modifies the passage of the tape where it passes through the obturator foramen with the theoretical advantage of reducing bladder injury. Third generation are mini slings which were withdrawn in the UK due to reduced efficacy [38] although, they are still in use in other countries with some newer ones in development. The technique was initially described as being performed under sedation. However in the UK most cases are performed under general anaesthetic (source BSUG database presented in thesis).

The midurethral mesh tape was found to treat USI as effectively as colposuspension [55, 56] which, coupled with their relative ease of procedure, reduced surgical time and speedier recovery, led to them replacing colposuspension as the clinician perceived ‘gold standard procedure’ for SUI [57]. The Department of Health Hospital Episode Statistics (HES) showed that in 2001, midurethral mesh tape overtook colposuspension as the most frequently performed procedure for SUI in the UK [3].

The majority of females undergoing surgery for SUI in the 21st century received a midurethral mesh sling without consideration of other options.

iv. Last resort

The current practice in the UK is that if the above methods have failed and the patient requests further surgery then an artificial urethral sphincter could be offered by specialist centres. There is an increase in popularity of artificial sphincters in France [58]. If patients are not suitable for any procedures or decline surgery, containment options should be optimised such as appropriate pads, or a long-term catheter (urethral or suprapubic) could be offered.

Patient characteristics associated with outcomes

Various studies have looked at outcomes of stress incontinence surgeries with regards to risk of failure of SUI, persistence or worsening OAB and de novo OAB.

Patient factors that increase risk of failure of MUS include increased age [59-69], increased BMI [59, 63, 67, 69-73], presence of comorbid conditions [59] in particular diabetes [67, 72, 74], neurogenic disease [75], chronic use of psychotropic medication [60], taking OAB medication [61, 73], postmenopausal status [67, 76] and concurrent prolapse [61, 74]. Previous gynaecological history that increases risk of failure of MUS include vaginal delivery [77], greater parity [77], macrosomic baby, prior hysterectomy or prolapse surgery [67, 76], prior continence surgery [59, 60, 72, 75, 78, 79], and concomitant surgery [59, 75]. Specific urogynaecological history points that have been noted to increase risk of failure of MUS include pre-operative smaller bladder capacity [66, 68, 76], larger volume of pre-operative pad test [59, 76], >2 pads per day before treatment [60], overactive bladder symptoms [66, 68, 72], nocturia [66], higher baseline leakage [59], more severe baseline symptom scores (Urogenital distress inventory (UDI), Incontinence impact question (IIQ), and MESA questionnaires) [59] [70], q-tip excursion and maximum straining angle of < 30° suggesting urethral hypomobility [59, 80] and higher Brink score (measure of pelvic floor strength) [59] [81]. Urodynamic parameters found to increase the risk of failure to cure SUI include lower bladder volume at first leak [82], low abdominal leak point pressure (ALPP) <60 cm/H_2O [70], maximum detrusor pressure during the voiding phase ≤29 cmH_2O [71], detrusor overactivity [64, 68, 73, 83], intrinsic sphincter deficiency (ISD) [72] [65, 67, 75, 80], low preoperative maximum urethral closure pressure (MUCP) [75, 76, 80, 83-

85], and low/<60cm/H_2O preoperative Valsalva leak point pressure (VLPP) [73, 84, 85]. Independent predictors of postoperative dissatisfaction were urgency symptoms [60, 70] and the need for a re-intervention [60].

Risk factors for persistence of OAB following MUS have been identified to be increasing age [62, 86], prior hysterectomy [86], preoperative OAB [60, 64], coexistent DO [64], lower bladder volume at DO [86], low bladder capacity [86], small voided volume [64], nocturia [86], lower urethral closure pressure [86], lower maximum flow rate [86] and increased baseline symptom severity [64, 68, 87]. Concomitant apical surgery was found to decrease the risk.

Risk factors for de novo OAB have been identified to be small bladder capacity [88], higher bladder outlet obstruction index [88], ISD [89], previous stress incontinence surgery [89], increased Pdet on filling of urodynamics [90] and previous prolapse surgery [89], whereas the risk was reduced with performing concomitant apical prolapse surgery [89].

Some of these however were found to be unrelated to failure in other studies [91, 92] but these would all be points to consider to be predictors.

For bulking agents, the risk factors for failure included higher pre-operative severity of urinary incontinence, higher pad weight [93], and pre-operative antimuscarinic use pre-operatively [94]. A high-volume surgeon had a higher chance of cure and a lower risk of 30 day contact with the hospital [94].

For AFS and Burch colposuspension, risk factors for failure of SUI surgery include severity of urge incontinence symptoms [95], prolapse [74, 95], diabetes [74] and being post-menopausal without hormone therapy [95]. There was an increased need for treatment of post op urge incontinence following AFS and colposuspension in patients with increased pre-op urge, DO, and prior anticholinergic medication [96]. Higher urge scores predicted failure by nonstress specific outcomes [95].

Following an AFS, previous prolapse increased the risk of de novo urgency [97] and there were decreased satisfaction scores with increased BMI and age [69].

It is unclear whether pre-operative PFMT improve the outcomes post operatively as there is limited evidence. A Cochrane review in 2015 found no trials related to this [98] and since then two trials have been identified which did not show any post operative benefit of pre-operative pelvic floor muscle training compared to no training [99, 100]

Risks of procedures

All operations come with risks and this risk profile varies with each procedure. Potential risks and complications [101] are:

- Infection - skin, urinary, intra-abdominal
- Bleeding
- Damage to other structures such as urethra, bladder, ureters, bowel, blood vessels, nerves
- Hernia formation at site of fascial incision – AFS and Colposuspension
- Pain – short term operative trauma related pain or long-term chronic pain including dyspareunia

- Failure to improve symptoms
- Recurrence of symptoms
- Urinary retention
- Deterioration in urinary symptoms (other than SUI)
- Rectocele with colposuspension

A few authors have studied risks for bladder injury during midurethral slings with varying rates of 3-9% and found that risk of injury is increased with lower BMI [102-104], endometriosis [104], younger age [103], RPT compared to TOT [102, 103], inexperienced surgeon [102], rectocele [102], local anaesthesia [102], previous caesarean section [102], and previous colposuspension [102].

As can be seen, multiple studies have looked at MUS, but there are fewer papers published regarding AFS and colposuspension and these papers tend to be older as there have been less recent trials on these due to the popularity of the mesh tapes. The most recent review on effectiveness and safety of continence surgery [21], found that the majority of the 175 trials included had high risk of bias and the authors suggested that there is value in undertaking further research. They report that trials are unlikely to be feasible to identify these adverse events and suggest promoting awareness and reporting and monitoring of complications and a database could be used for this.

Outcomes

It is important to assess the outcome of any intervention, to ensure it is effective, and this can be achieved using an objective or a subjective tool. An objective measure is usually obtained by a healthcare professional and can be a clinical finding or an investigation result so tends to be more reproducible than a subjective measure. A subjective measure is generally patient reported so can be influenced by personal feelings and opinions.

There can be considerable difficulty in assessing continence outcomes as it is multifaceted and patient dependent, compared to other medical conditions where a laboratory test may be an appropriate outcome. This has resulted in multiple outcome measures for female incontinence; 119 were found by a recent systematic review [105], with no consensus as to which is 'the best'. For continence, patient reported outcome measures (PROM) are important, as symptomatic improvement with improved QOL is the reason for performing surgery [106] however again these are very numerous with a recent review identifying 24 different validated questionnaires (Figures 5 and 6) [107, 108]. The most frequently found was International consultation on incontinence questionnaire short form (ICIQ-UI SF) (n=18) [109], patient reported global impression of improvement (PGII) (n=15) [110] and the Incontinence Impact Questionnaire (n=8) [105]. The lack of a standardised outcome is a barrier to meta-analysis [98].

An alternative measure can be used is Patient Reported Experience Measures (PREMs) which allow patients to provide direct feedback about the care they received. They measure patients' perspectives of their experiences and aim to drive improvement in services. These may be important in stress urinary incontinence as

some patients find it a difficult topic to talk about [111] and having an open and easy discussion can help patients to make the most appropriate choice.

Objective outcome measures
Cough stress test (CST)
1 hour pad test
24-hour pad test
3 day voiding diary
Incontinence episode frequency (IEF) per week
Pad number/other incontinence aids per day
Post void residual (PVR)
Uroflowmetry and PVR
Modified Oxford grading scale
Electro-myography and Perineometer

Figure 5: Objective outcome measures used to assess urinary incontinence [107]

Subjective outcome measures
Validated questionnaires
International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF)
Patient Global Impression of Improvement (PGI-I)
Incontinence Impact Questionnaire (IIQ-7)
Incontinence Quality of Life (I-QoL)
Incontinence Severity Index (ISI)
Urogenital Distress Inventory (UDI-6)
ICI Questionnaire -Lower Urinary Tract Symptom Quality of Life (ICIQ-LUTSqol)
King's Health Questionnaire (KHQ)
Pelvic Organ Prolapse/Urinary Incontinence Sexual Function Questionnaire Short Form (PISQ-12)
Bristol Female Lower Urinary Tract Symptom (BFLUTS)
EQ-5D
Patient Global Impression of Severity (PGI-S)
Patient Perception of Intensity of Urgency Scale (PPIUS)
Birmingham Bowel Urinary Symptom-22 questionnaire (BBUQ-22)
Urgency Perception Scale (UPS)
International Consultation on Incontinence Questionnaire-Overactive Bladder (ICIQ-OAB)
Australian pelvic floor questionnaire (AFPQ)
Short-Form 12 (SF-12)
Incontinence Outcome Questionnaire (IOQ)
Female Sexual Function Index (FSFI)
Urinary Incontinence Severity Score (UISS)
International Consultation on Incontinence Questionnaire-Female Sexual Matters associated with Lower Urinary Tract Symptoms (ICIQ-FLUTSsex)
Pelvic Floor Impact Questionnaire (PFIQ-7)
Stress Incontinence Index and Quality of life Index (SII)
Non-validated questionnaires or other subjective outcomes
Subjective satisfaction/improvement/success/leak
VAS
Other
ICIQ-UI SF Question 5

VAS, visual analogue scale.

Figure 6: Subjective outcome measures used to assess urinary incontinence [107]

Mesh Pause

During the early to mid 2010s, emerging reports of mesh related complications [112, 113] led to concern about midurethral mesh slings. Complications observed following mesh procedures included immediate operative complications such damage to organs, vessels or nerves during placement of the mesh, or later complications such as mesh exposure into the bladder, urethra, vagina or bowel, voiding dysfunction, dyspareunia or chronic pain [112, 113]. These concerns culminated in a government enforced 'mesh pause', in July 2018, which was a situation unique to the UK, where the use of vaginal mesh in procedures was temporarily banned while an independent enquiry was undertaken. The results of this review and recommendations are published in the Independent Medicines & Medical Devices Safety Review, commonly known as the Cumberlege report [114] as it was led by Baroness Cumberlege and it lists a set of requirements to be met before mesh can be re-instated Table 3).

Cumberlege criteria for re-instatement of mesh

The conditions needed to be satisfied before a lifting of the pause could be considered were:

- Surgeons should only undertake operations for SUI if they are appropriately trained, and only if they undertake operations regularly;
- They report every operation to a national database;
- A register of operations is maintained to ensure every procedure is notified and the woman identified who has undergone the surgery;
- Reporting of complications via the Medicine and Healthcare products Regulatory Agency (MHRA) is linked to the register;
- Identification and accreditation of specialist centres for SUI mesh procedures, for removal procedures and other aspects of care for those adversely affected by surgical mesh;
- NICE guidelines on the use of mesh for SUI are published

Table 3: Cumberlege criteria for re-instatement of use of vaginal mesh in surgery in the UK [114]

Figure 7 shows the comparison of SUI surgery recorded on the BSUG database before and after the mesh pause (data retrieved from BSUG for an additional project, figure produced by this author). The top bar shows surgeries completed in the year 2017, dominated by mid urethral mesh tapes, compared to the surgeries for the first six months of the mesh pause (1/8/18 – 31/1/19), dominated by PUB.

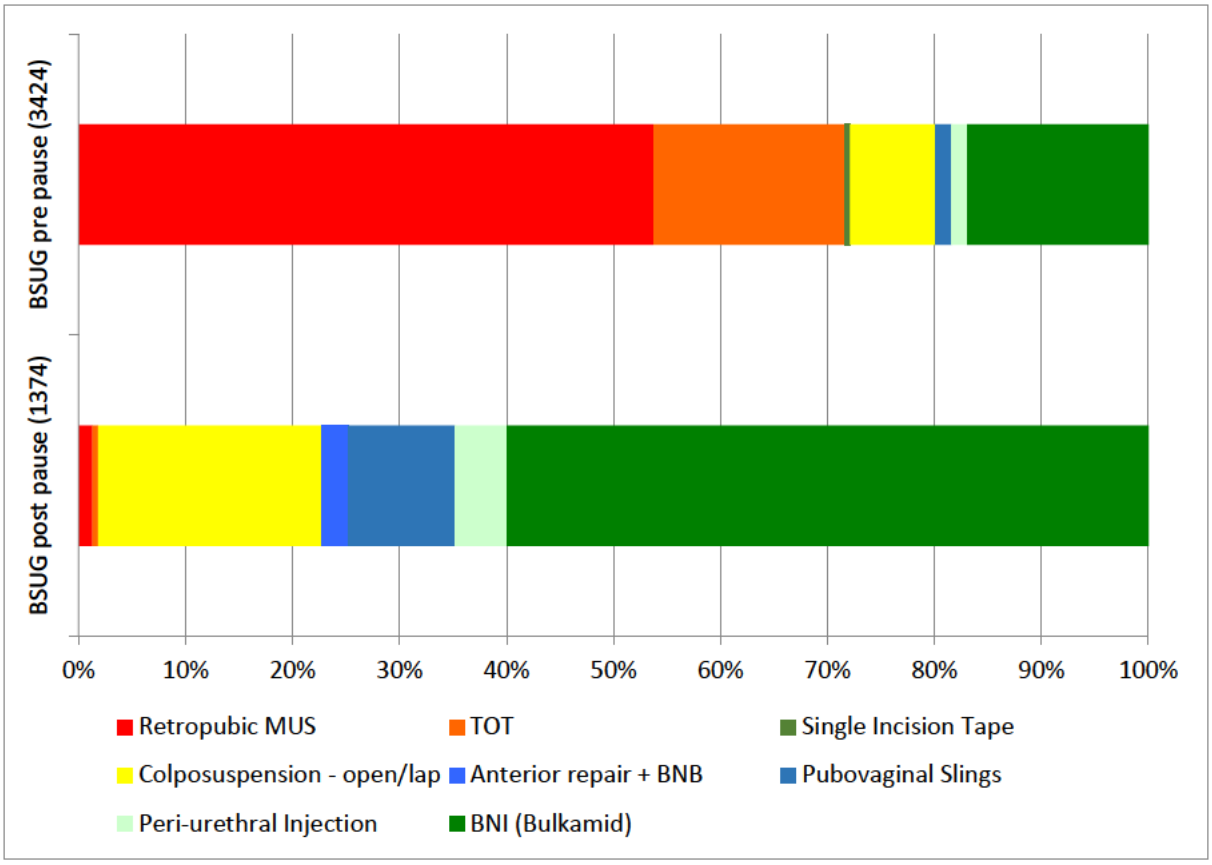


Figure 7: Trends in SUI surgery entered onto the BSUG database before (top bar) and after (bottom bar) mesh pause

The data demonstrate that the mesh pause resulted in a huge increase in PUB and a resurgence of the older surgical techniques to treat SUI and therefore a reconsideration of which patients should receive which treatment. This, coupled with uncertainty about the future of mesh, has led to an increased need for evidence of the outcomes of each procedure. Ultimately patients need to be informed of the options, risks and alternative treatments, to comply with Montgomery ruling as part of the consent process [115].

The Cumberlege review is ongoing and the situation is, at the time of writing, unresolved with the criteria for reinstatement not being met [114]. The lack of an appropriate registry or database remains to be one of the obstacles to re-instatement. The BSUG database is a potential vehicle for this.

BSUG database overview

Background

The BSUG database records patients characteristics, surgical procedures and outcomes and is recommended by several bodies, including NICE [12] and NHS England [116-118]. However, at the present time, participation and data entry on the database, is voluntary (non-mandatory).

The BSUG database was originally designed in 1999 as an audit tool for incontinence procedures, allowing clinicians to record their own results. Initially the idea was thus to support self-regulation and over time the database has evolved into a national database for BSUG members [119, 120]. An interview with the founder of the database (PM) was performed for this thesis to gain a full understanding of its evolution and this is described below.

Ethicon Gynaecare (a subsidiary of the pharmaceutical company Johnson and Johnson responsible for manufacturing the mesh and mid-urethral tapes) approached PM to set up a database to collect incontinence surgery data. This was following his involvement with establishing the first UK national training centre for mid-urethral tapes in 1998. He was an Ethicon Gynaecare TVT™ (Tension free vaginal tape) national trainer and as part of this role, in 2000, he set up a database for this procedure using an educational grant from the company. At inception, the database was specifically for TVT data collection *only,* with pre, intra and post-operative details collected. Shortly after this, the Chair of the Audit Committee, from the recently established BSUG society, approached PM to expand this database to make it nationally available and to cover all urogynaecology procedures. Funding was taken

over by BSUG as it was felt to be inappropriate to have the funding linked to industry. The database used Microsoft Access and was on CD-ROM, as this was prior to the internet being widely available. All members of BSUG were invited. The blank CD was posted to participants, the data was entered locally and returned yearly to the newly established BSUG audit committee. The audit committee were responsible for amalgamating the data. Engagement with the database was poor initially with 4 users at the end of 2005, equating to 2000 patients' records. PM described the reason for the lack of data entered, as "*people were uninterested*".

PM became Chair of the BSUG Audit Committee in 2005 and with a grant from BSUG, developed an internet-based audit database for incontinence and prolapse surgery. This was called "BSUG.net" and was launched on a secure internet site in March 2007 with endorsement from NICE. There was an option for clinicians to enter data retrospectively, so entries are seen prior to this date. From the outset, patients were asked for written informed consent for their data to be entered on the database. In 2007, an application was made to the Patient Information Advisory Group (PIAG) for section 60 exemption to allow data entry without patient consent. This was declined and thus entry on the database continued to be permitted only after written informed consent had been given by the patient [121] (appendix 2).

The database was established as a limited company (BSUG database Ltd) in March 2009 with PM as Director and those holding executive committee posts being the other company executives. This led to the establishment of intellectual property (IP) rights and software contracts. There was a move to NHS N3 network (in conjunction with

The IceWay: ICE ICT and Everyman Legal Solicitors) to ensure data security. This means the database complies with General Data Protection Regulations (GDPR).

Since 2012, the database has been required for units who wish to become accredited with BSUG with a minimum of 90% of patients entered and 60% of outcomes completed. Accreditation is designed to identify units that deliver best practice with the view to being of value to service users and commissioners [122] and is largely related to the organisation and standards of care in urogynaecology units.

At the time of writing, the BSUG database was widely used with over 250 registered users in the UK who record surgical activity and outcomes, for urinary incontinence and pelvic organ prolapse. Access to the database is free for all BSUG members (paid subscription) [123]. One of the drivers for registration being BSUG accreditation, which mandates use with targets for data collection. Not all continence procedures are captured as only members of BSUG are able to enter data thereby excluding urologists and gynaecologists who chose not to be BSUG members. Previously, urologists could chose to enter data onto the British Association of Urological Surgeons (BAUS) database [124]. However this has now closed and in future urologists may have access to the BSUG database [125]. BSUG estimate, using HES data, that from April 2008 to March 2017, 40% of continence procedures in England were captured [126] and from April 2017 to March 2019 the estimate was 60% [22].

Additionally there is the International Urogynaecology Association (IUGA) database. This launched in January 2017. It currently has 294 international users and 4496 procedures entered (personal communication with IUGA Apr 2022). It is largely based

on the BSUG database and is available for all IUGA members [127]. The options for procedures entered available are the same with some additions to ensure all mesh products from different countries are included. The outcomes recorded are the same.

Data collection

For the BSUG database, pre-operative patient characteristics (table 4), surgical details, (table 5) (figure 8) and complications, are entered by the consultant, or deputy, at the time of the operation, with outcomes (figure 9) and post-operative complications (table 6) recorded at follow up. Outcomes are clinician and patient reported (table 7), including patient reported global impression of improvement (PGII), change in SUI and change in OAB [128, 129]. These are questions asked to patients at routine post operative review clinic. PGII is a Likert scale which includes the outcomes very much better (VMB), much better (MB), a little better (LB), no change (NC), a little worse (LW), much worse (MW) and very much worse (VMW). These are grouped into “better” which includes VMB and MB and “not better” which include LB, NC, LW, MW and VMW [130]. Outcomes for change in SUI include whether SUI is cured, improved, no change or worse. Outcomes for change in OAB include whether it is cured, improved, no change or worse or additionally whether it is new or never present. There is no defined way to ask these questions and data could be collected by the surgical team of another member of the wider team. Follow up is variable between 6 weeks to 12 months according to clinician practice. There are no mandatory fields and data entries are not validated.

Pre-operative data entry

- Age
- BMI
- Were pelvic floor exercises offered. If yes – who were they supervised by?
- Were Urodynamic studies performed and if yes – what was the diagnosis?
- Was procedure specific information literature given?
- What was the Pelvic organ prolapse quantification (POP-Q) or other prolapse grade? (Used to quantify prolapse on vaginal examination)
- Previous Surgery
- Parity
- Pre-surgery quality of life questionnaires from International consultation on incontinence questionnaire (ICIQ) [109]
    - ICIQ-UI (urinary incontinence) Short form
    - ICIQ-VS (vaginal symptoms) & ICIQ-SM (sexual matters)
    - ICIQ-LUTS QOL (lower urinary tract symptoms quality of life)
    - ICIQ-OAB
- electronic Personal Assessment Questionnaire (ePAQ) [131]

Table 4: Pre-operative data collected for the BSUG database

Surgical data entry

- Operation date
- Surgery
    - First/redo (repeat)
- Concomitant surgery – additional major procedures performed at the same time as the index incontinence procedure
- Mesh
- Anaesthetic
- Grade of operator/supervisor
    - Consultant
    - Associate specialist [132]
    - Subspecialty trainee
    - Specialty trainee
    - Staff grade [132]
    - FTSTA
    - Other
- Intraoperative complications
    - Ureteric injury
    - Urethral injury
    - Bladder injury
    - Bowel injury
    - Vascular injury
    - Neurological injury
    - Blood loss > 500ml
    - Peri-operative blood transfusion
    - Peri-operative Thromboembolism
    - Death
    - Vaginal Button-holing (added later)
    - (Graft Complication – if applicable)
- Estimated blood loss
- Operation duration

Table 5: Surgical data collected for the BSUG database

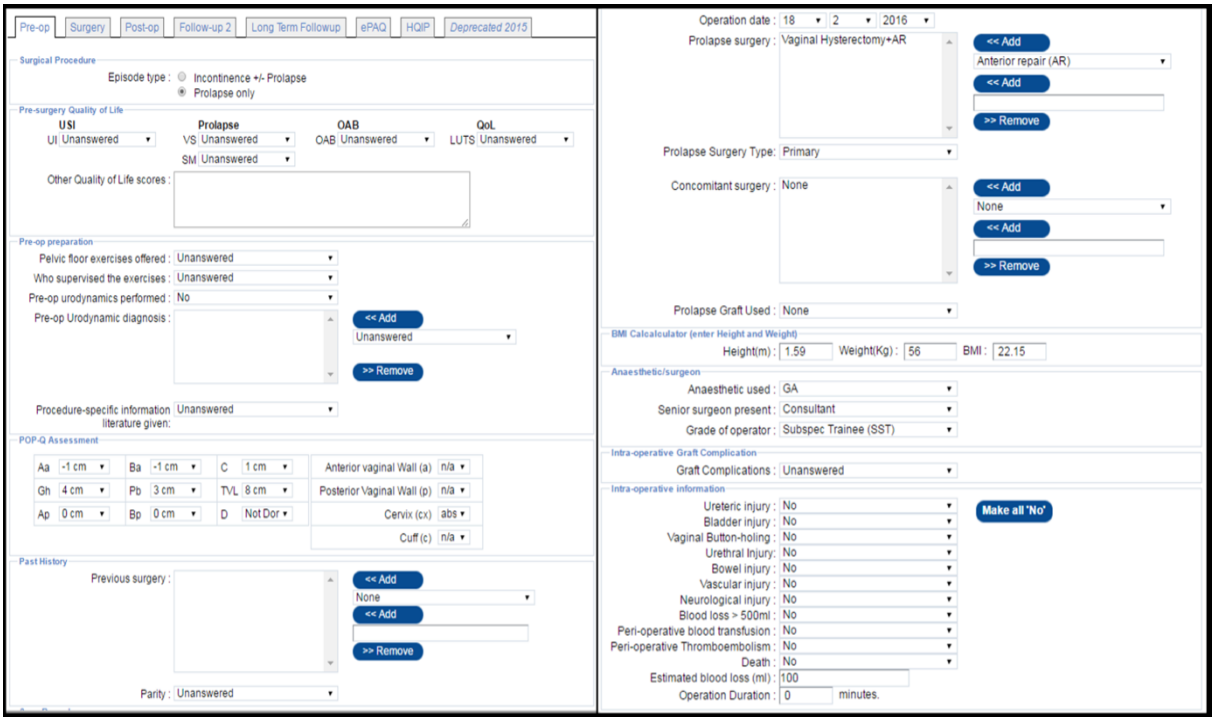


Figure 8: BSUG database appearance: pre-operative and intra-operative data

Post-operative period

- Return to theatre within 72hr
    - Active bleeding, Drainage of haematoma, Bowel injury, Bladder injury, Ureteric injury, Voiding difficulty, Other
- Catheterisation >10 days
- Return to hospital within 30 days
    - Trial without catheter, Voiding difficulty, Constipation, Infection, Active bleeding, Haematoma, Bowel injury, Bladder injury, Ureteric injury, Other
- Readmitted to Hospital within 30 days
    - Trial without catheter, Voiding difficulty, Constipation, Infection, Active bleeding, Haematoma, Bowel injury, Bladder injury, Ureteric injury, Other

Table 6: Post-operative data collected for the BSUG database

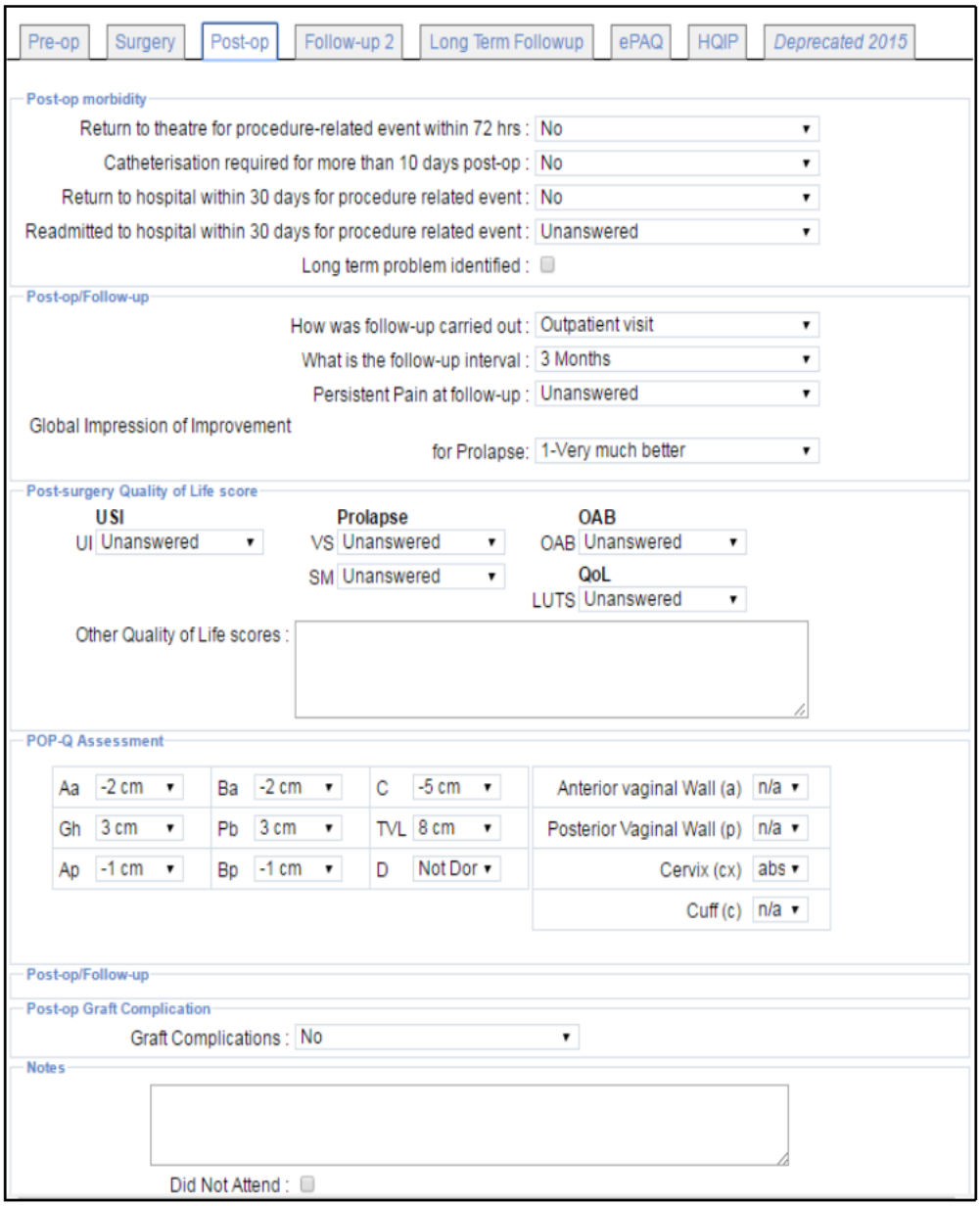


Figure 9: BSUG database appearance: post-operative data

Follow up

- Method
  - Outpatient visit
  - Postal questionnaire
  - Online questionnaire
  - Telephone follow-up
  - GP practice
  - Other individual preference
- Timing
  - 6 weeks
  - 3 months
  - 6 months
  - 1 year
- Persistent pain at follow up
- Post-surgery quality of life questionnaires (repeated version of pre operative)
  - ICIQ-UI Short form, ICIQ-VS, ICIQ-LUTSqol, ICIQ-OAB,
- ePAQ
- Post op POP-Q or other prolapse grade?
- Post op graft complication
- Patient-reported global impression of improvement of incontinence (PGII) [110] recorded on a Likehert scale of:
  - Very much better (VMB)
  - Much better (MB)
  - A little better (LB)
  - No change (NC)
  - A little worse (LW)
  - Much worse (MW)
  - Very much worse (VMW)
- Change in SUI and OAB recorded under the following headings [128, 129].
  - Cured
  - Improved
  - No change
  - Worse
  - New symptom
  - Never present

Table 7: Urinary incontinence outcomes recorded at follow-up on the BSUG database

Computer and security

The BSUG database can only be opened on NHS (N3 connected) computers. It is password protected and is accessed by web browser and runs on a 256 AES SSL connection. Security is run by Daisy Communications (IGSoC and ISO27001 accredited). All data is encrypted to NHS standards.

Data protection

Prior to being eligible to enter cases onto the database, centres must fulfil requirements set out by the Caldicott Guardian (Data protection). Each hospital has a Caldicott guardian who is a senior person responsible for upholding the Caldicott Principles (table 8) which include protecting the confidentiality of information on health and care [133]. This works in conjunction with the Data Protection Act which incorporates the GDPR. Caldicott principles should be followed to protect individuals when identifiable data is held such as their name, date of birth or address. They also relate to how that information can be used and shared. Currently under UK law, individual patients are required to give consent (see appendix 2) before their anonymised data can be included in the database and are made aware that it can be used for research and audit. Additional ethical approval is not required for research as this permission had already been granted to each centre.

There are 7 Caldicott principles which must be upheld by the Caldicott Guardian.

1. *Justify the purpose for using all confidential information*
2. *Only use personal confidential data if absolutely necessary*
3. *Minimise the use of personal confidential data*
4. *Confidential data should only be available to those that actually need to see it and limits should be put in place to reduce access*
5. *Those with access to personal confidential data must be aware of the responsibilities they have to protect it*
6. *Only lawful uses of confidential data should be undertaken*
7. *Information can and should be shared in the best interests of patient as long as these principles are upheld*

Table 8: Caldicott principles [133]

Uses of BSUG database

The data from the BSUG database is currently used on an individual or centre level for clinician appraisal, internal audit and quality control, and on a national level for countrywide reporting and research. In a clinical setting it can be used for counselling patients. The database has never had a regulatory capacity.

The original purpose of the BSUG database was an audit database allowing consultants and units to collect data to review their practice. Currently, reports can be generated by clinicians to detail the number of procedures done, the complications reported, and the outcomes given. These data can be used in appraisal to examine practice, establish professional development goals and could identify if targeted training is required. Long term personal data from a surgical database can be useful if a clinician experiences complications, as previous data can be examined to assess if it is a random cluster of complications rather than a longer standing concern. The standard operating procedure (SOP) for the BSUG database, states that practitioners may choose how they use their own *individual* dataset within their Trust's governance framework [134].

When this work started, there was no national reporting, with the first report being published in 2018. The report includes trends of procedures performed, unadjusted outcomes and complications [22]. The SOP states the primary use of the *national* dataset is for simple data description, audit and trends, so internal and external approval for this is not required. It states in future there is the possibility to create benchmarks thus giving it a major role in patient safety [135]. The process of benchmarking centres with respect to complications is complex and fraught with

potential bias. A secondary function of the *national* dataset is for use in research [136] and for this, proposals must be approved by BSUG Committees [134]. Data Protection Laws and Caldicott Principles will always be followed.

Surgical outcome data from a surgeon or a centre as recorded on the BSUG database can be used during the counselling process in graphical form to demonstrate outcomes (Figures 10-15) and complications (Figure 16) to the patient. The clinician can generate these in real time in the clinic. They can be categorised using patient characteristics in a step towards personalised medicine. The following are examples of how data can be demonstrated to patients during a consultation.

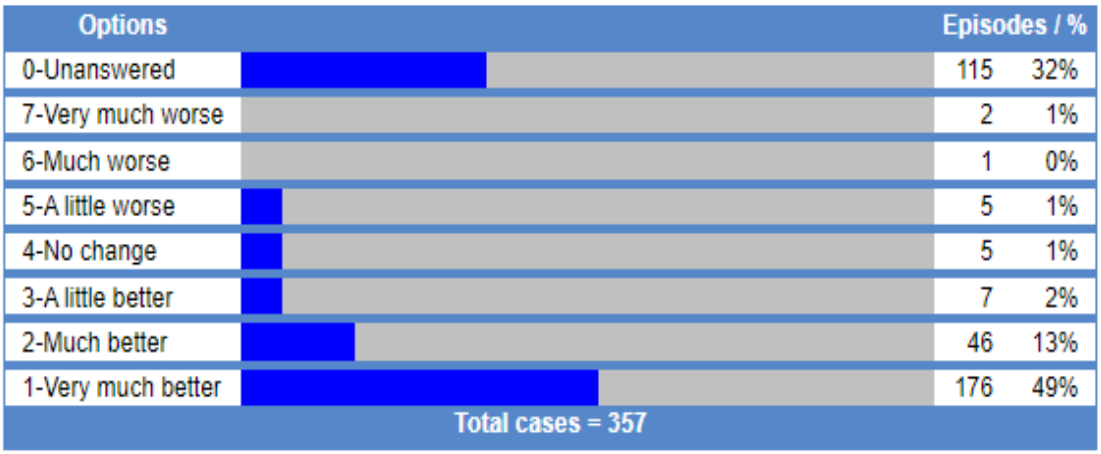


Figure 10: Histogram to show PGII outcomes for RPT generated by a clinician in real time

	Total	<20	20-24	25-29	30-34	35-39	40-44	>=45
0-Unanswered	115	12	28	36	22	10	5	2
7-Very much worse	2			1	1			
6-Much worse	1				1			
5-A little worse	5		1	2	2			
4-No change	5		1	1	3			
3-A little better	7	1	1	4		1		
2-Much better	46	3	5	17	16	3	2	
1-Very much better	176	19	31	72	35	15	4	
Total cases = 357								

Figure 11: Table to show PGII outcomes for RPT by BMI generated by a clinician in real time

	<20	20-24	25-29	30-34	35-39	40-44	>=45
0-Unanswered	12	28	36	22	10	5	2
7-Very much worse			1	1			
6-Much worse				1			
5-A little worse		1	2	2			
4-No change		1	1	3			
3-A little better	1	1	4		1		
2-Much better	3	5	17	16	3	2	
1-Very much better	19	31	72	35	15	4	
Total cases = 357							

Figure 12: A visual representation of the table above to show PGII outcomes for RPT by BMI generated by a clinician in real time

Options	Episodes / %	
Unanswered	117	33%
Worse	1	0%
No change	5	1%
Improved	40	11%
Cured	186	52%
Never present	8	2%
Total cases = 357		

Figure 13: Histogram to show Change in SUI outcomes for RPT generated by a clinician in real time

	Total	<20	20-24	25-29	30-34	35-39	40-44	>=45
Unanswered	117	12	28	35	23	12	5	2
Worse	1			1				
No change	5		1	1	2	1		
Improved	40	3	6	16	11	2	2	
Cured	186	19	30	78	41	14	4	
Never present	8	1	2	2	3			
Total cases = 357								

Figure 14: Table to show Change in SUI for RPT by BMI generated by a clinician in real time

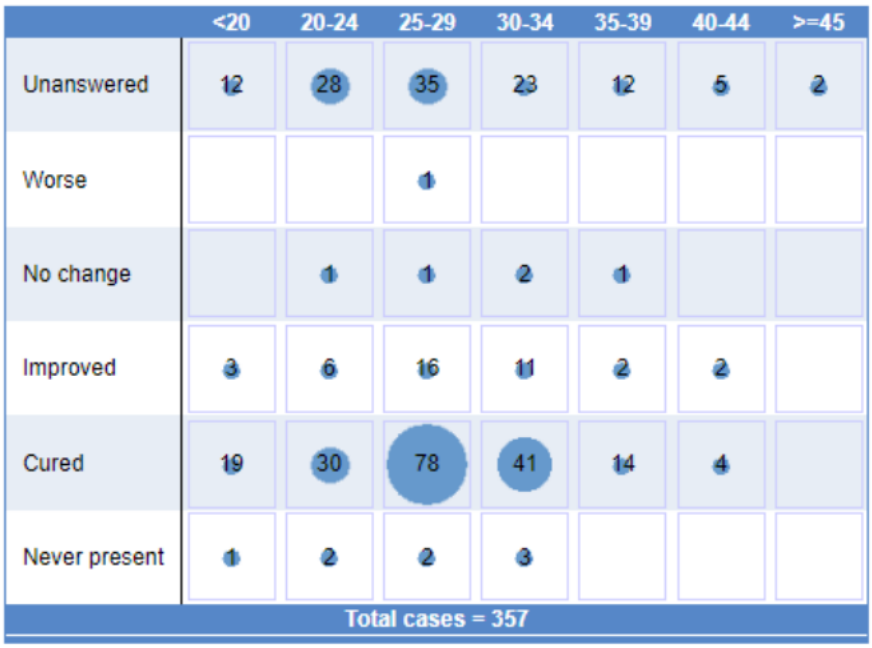
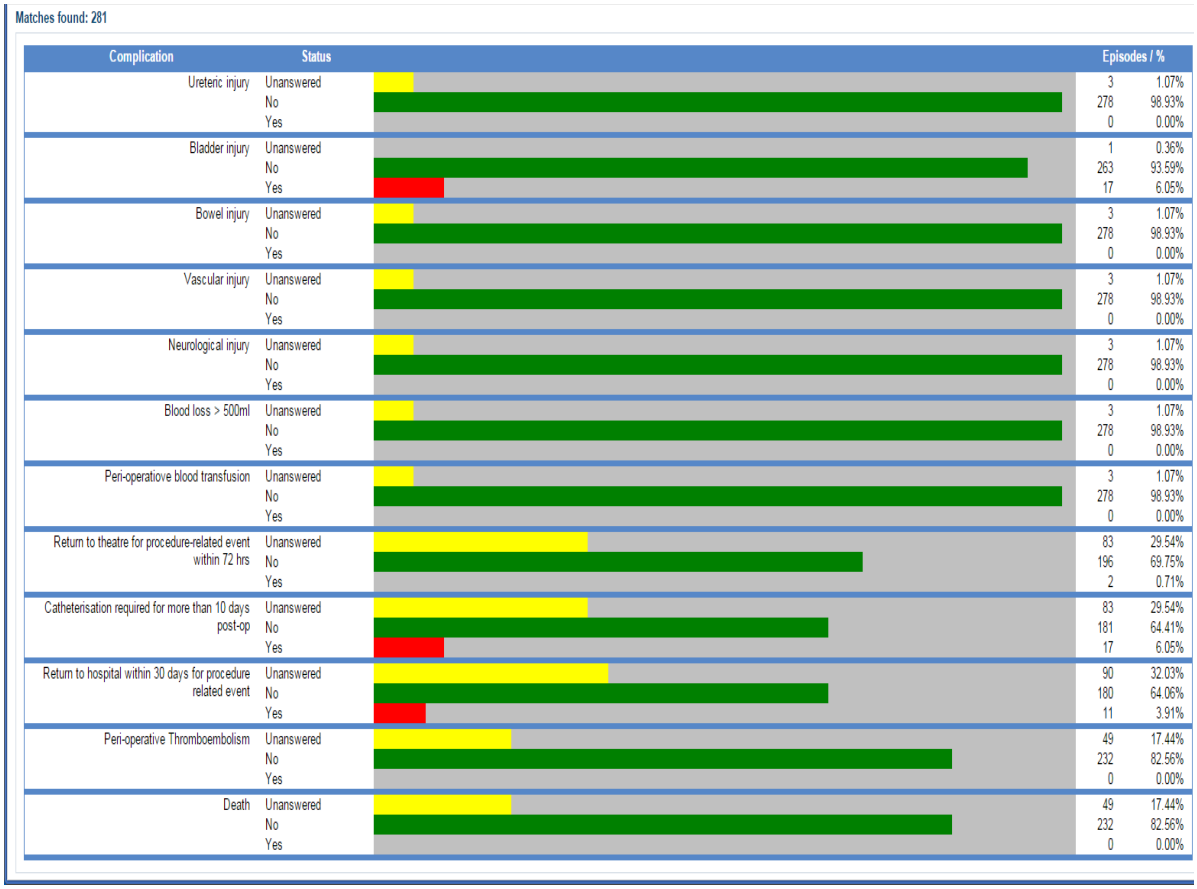


Figure 15: A visual representation of the table above to show change in SUI outcomes for RPT by BMI, generated by a clinician in real time



Matches found: 281

Complication	Status	Episodes	%
Ureteric injury	Unanswered	3	1.07%
	No	278	98.93%
	Yes	0	0.00%
Bladder injury	Unanswered	1	0.36%
	No	263	93.59%
	Yes	17	6.05%
Bowel injury	Unanswered	3	1.07%
	No	278	98.93%
	Yes	0	0.00%
Vascular injury	Unanswered	3	1.07%
	No	278	98.93%
	Yes	0	0.00%
Neurological injury	Unanswered	3	1.07%
	No	278	98.93%
	Yes	0	0.00%
Blood loss > 500ml	Unanswered	3	1.07%
	No	278	98.93%
	Yes	0	0.00%
Peri-operatiove blood transfusion	Unanswered	3	1.07%
	No	278	98.93%
	Yes	0	0.00%
Return to theatre for procedure-related event within 72 hrs	Unanswered	83	29.54%
	No	196	69.75%
	Yes	2	0.71%
Catheterisation required for more than 10 days post-op	Unanswered	83	29.54%
	No	181	64.41%
	Yes	17	6.05%
Return to hospital within 30 days for procedure related event	Unanswered	90	32.03%
	No	180	64.06%
	Yes	11	3.91%
Peri-operative Thromboembolism	Unanswered	49	17.44%
	No	232	82.56%
	Yes	0	0.00%
Death	Unanswered	49	17.44%
	No	232	82.56%
	Yes	0	0.00%

Figure 16: Complications of RPT recorded on the BSUG database – the first 7 are intra-op, the next 5 are post operative

Expanding the uses of the BSUG database

As described above, the current BSUG database is primarily for individual audit and demonstrating outcome and complication data to patients. This thesis aims to determine whether the BSUG database could be used for understanding variations in outcomes of surgery for Stress Urinary Incontinence. It is thus important to understand what the requirements of a database would be in this instance and the limitations of data within databases.

The Perfect Database: in an Imperfect World

The perfect database would be 100% completed with accurate, validated information which avoids bias but requires no additional efforts by clinicians or patients. The database would have a clear aim endorsed by all stakeholders and regularly report live relevant data while being responsive to a rapidly changing medical world.

To design the perfect database a clear plan is required, and the purpose of the database must be defined. The 'outcome objective' must be understood as design and conditions of the database depend on this. The data points required, method of data capture and the way the data is to be used must be determined.

When a database is designed it is important to consider whether it would measure a single intervention or the whole cycle of care, from presentation of the condition, through all management strategies and beyond, to capture long term data and complications, known as a disease based database.

Data collection

Selected data points should contribute to the ‘outcome objective’. Consideration can be given to having a core outcome set (COS) with additional optional extended datasets. Core data give the minimum data that is sufficiently detailed yet not overly cumbersome to ensure completion rates are high. Additional points, added for special interest, can overburden the database so ideally remain optional. Data points can be determined from pre-defined criteria or expert opinion such as in a Delphi approach [137, 138]. Additional data may be collected for a limited period of time to answer specific questions such as with the MBRRACE-UK (Mothers and babies: Reducing risk through audits and confidential enquiries across the UK) [139]. An additional field is easy to include during the design phase but more difficult when the database has been launched. Completion can be optimised by it being mandatory and audited [140] with appropriate follow up particularly if used for incident reporting or as a regulatory position such as benchmarking [141].

Data must be easy to record on all devices intended for use, such as a phone or computer. The data capture must be suitable for the target audience, either patient or clinician, and use precise, unambiguous language. Pre-defined options for inputs rather than free text are easier for the user to complete, avoid typographical errors and are subsequently easier for the data analyst. Free text has additional challenges during analyses in view of multiple possible answers and potential spelling mistakes. GDPR requirements must be adhered to.

Simple audits of numbers of cases, outcomes and complications can be performed and consideration to more complex analysis given.

Handling missing data

Missing data is inevitable in database analysis therefore strategies are required to maximise available data and minimise bias associated with this. One option is to delete all non-complete cases known as *listwise deletion* [142]. This results in a reduction in the number of cases available for analysis therefore has the potential to reduce the power of the analysis. However, provided the incomplete cases are a random selection of total cases risk of bias is minimal. If the incomplete cases were linked there is the potential for introduction of bias. *Pairwise deletion* similarly excludes cases where the data is missing but is more selective [142]. If a case has some missing data but this data would not have been required for the particular analysis then it can still be included, but if the missing data point is required for a different analysis, then it will be excluded from that one. This method maximises the data while remaining relatively simple.

Imputation is a more refined way to overcome missing data [142], however requires complex statistical input and the associated resources required for this. Missing data are substituted with an estimated value based on other relevant data. The imputations can be single or multiple. Historically hot deck or cold deck methods were used to fill the gaps with single data points from the existing datasheet or from a similar cohort, but with the increases in computer power these have been superseded by other methods less likely to introduce bias. Mean imputation replaces the missing value with a mean of all the other values which has the benefit of not changing the overall mean and works well for univariate analysis but not for multivariate analysis. To overcome problems with other methods, Rubin developed multiple imputation [143]. The first stage of this is where instead of a single imputation, multiple datasets (m) are

produced from multiple imputed values. All datasets (m) are analysed, and the results are pooled to calculate the mean, variance, and confidence interval. The benefit of multiple imputations is that it can be applied to cases where the missing data is not random as well as in cases where it is missing at random.

Uses of data analysis from databases

Successes of databases

Databases allow for evaluation of heterogenous clinical practice which contributes to 'real world' evidence. There are national mandatory databases in the UK with high level NHS support that have achieved improvements in patient safety and robust audit.

The cardiac surgeons started to record cardiac surgery mortality rates in 1977 [144] with an initial crude attempt to compare units. Further patient details were added, to allow risk adjusted outcomes to be generated in 1994 [145] and surgeon specific outcomes were first published in 2005 [146]. Now, all cardiac operations performed in NHS trusts in England and Wales are included in the National Cardiac Audit Programme (NCAP) [145] run by the National Institute for Cardiovascular Outcomes Research (NICOR) overseen by HQIP [147] on behalf of NHS England. Reports are published by the Society for Cardiothoracic Surgery (SCTS) [146] where hospital and individual consultant surgeons' risk adjusted outcomes are compared to national benchmarks and made publicly available in the "Blue Book" [148]. Individual surgeons need to ensure they stay within the statistical limits of good practice [149]. With over 500,000 operations recorded, the report shows that despite the population being older and more comorbid, in 15 years, they have been able to track a reduction in crude mortality from 4% to 2.8% for all cardiac surgery [149]. Data is self-reported by clinical teams and mortality checked against HES data with good agreement. Internal validation occurs when data is returned to be checked by clinical teams at the initial stages of analysis. External validation is not possible due to the volume of cases meaning it is not possible to visit all sites performing surgery. Previously, data was linked to Office for National Statistics (ONS) to track longer term survival, but this is

now not possible in view of tighter regulations with GDPR laws. By meticulous data collection, a drop in mortality has been observed and quality of all surgeons is measured.

The National Joint Registry [150], established in 2002 following the 3M Capital Hip Implant Failure Report 2001 [151], is the largest orthopaedic registry in the world with 3.7million records [152] and 17 year follow up data. Submission for NHS organisations has been mandatory since 2010 and data is validated by the hospital that enters it. Patients can decline consent but currently 96% of eligible patients are entered. It aims to improve patient care by recording, monitoring, analysing and reporting on outcomes in joint replacement surgery. It identifies how surgeons, hospitals and implants perform, allowing early action to be taken, if required, to improve patient safety and to locate patients who received specific implants if concerns are identified. Reports, available publicly, are produced yearly which show activity levels, trends in surgical practice and implant usage. Patient demographics are recorded and outcomes [153] for hospitals and individual surgeons are displayed including revision rates, and quality of life assessments, with a decision-making tool to help patients make informed decisions about their care. It supports manufacturers, with post market surveillance of implants to enable early warning schemes of poorly performing devices and to help surgeons chose the best implant for their patients depending on patient characteristics. It has led to cost savings with hips and knee implants to benchmark implant prices against performance and it feeds into Getting it right first time (GIRFT) Improvement support programmes [154]. It is funded through mandated annual hospital subscription charge and from industry. There is a full support network

including champion orthopaedic surgeons, compliance officers, a service desk and regional events with regular research performed [153] .

The National Cancer Registration and Analysis Service (NCRAS) [155] has automatic data entry from NHS hospitals, as the database has permission to collect patient data under Section 254 of Health and Social Care Act 2012 in order to protect the health of the population [156], although patients can opt out. It allows an oversight of prevalence of cancers, identification of patients at highest risk, stage at diagnosis, survival and mortality. It aims to improve diagnosis, screening, genetic testing, counselling and treatment efficacy, ultimately with the aim to plan and improve services. The objectives are to understand and reduce inequity and it provides data for research projects. Data can be compared internationally to ensure policies maximise survival rates and early diagnosis. Data is kept for at least the lifetime of the patient to detect long term trends or recurrences and for genetic information. Data is analysed to help clinical teams, academics, charities and policy makers to improve care. The data is checked by comparing it to other NHS digital records. Researchers and charities can apply to receive data for research, with 35 cancer publications from the data in 2020 [155, 157].

Huge observational studies can be created using increasingly innovative methods to minimise bias. The Veterans Health Administration (VA) and Medicare were utilised to study two medications for diabetes. Physician prescribing patterns were used to approximate an RCT with patients being randomised to the drug that their doctor normally prescribed and data was analysed to show one drug had higher hospitalisation and death than the other and clinical decision making was changed [158].

If observational data, such as in a database, can be linked to medical records a broad depth of information can be added to each patient. Clinical Practice Research Datalink (CPRD) [159] collects anonymised patient data from registered UK GP practices and is sponsored by National Institute for Health Research (NIHR) and Medicines and Healthcare products Regulatory Agency (MHRA). These data are linked to other health outcomes to provide ongoing population health data. This has been beneficial to inform clinical guidance, evaluate health policy effectiveness, to assess medicine usage, to investigate safety of drugs and to identify risk factors for disease. Enhanced computing now allows 'big data' from multisource electronic medical records and extended databases to become the norm to provide new health data for analysis on an individual, national and international level. This may, in the future, include self-entry data and social media or personal health data via apps to be used.

Urogynaecology databases: Other national databases

The DUGAbase [160, 161] is the Danish urogynaecology database. It was established in 2006 with the aim to monitor and improve the quality of urogynaecology surgery in Denmark [162]. It is part of the Danish Civil Registry System which is a national register containing personal and medical information on everyone who is registered as a resident in Denmark which generates an individual civil registration number (CPR number). The database is mandatory and part of a network of databases [163] run by the government, costing several million euros per year to fund, with an infrastructure of full-time secretaries and administrators. When an operation is performed, the hospital episode links to the CPR number and the clinician receives reminders until the database is completed. Patient consent is not required as it is mandated by the government and patients cannot decline. It captures data with minimal risk of bias or

non-reporting. It is close to 100% complete regarding percentage of cases entered, and has under gone validation where cases on the database were examined at random and the entries validated against the notes with a high (90%) accuracy rate [162, 164]. In Denmark many personal data items are recorded and "*this is just how it is – the government record lots of things and people don't mind. It has now just become a matter of course – it is part of the daily way of writing the note*s" (personal communication with Danish urogynaecologist 2018). There are annual reports that describe surgical numbers and outcomes with clinical quality indicators [164]. Published research includes papers on success rates [94], post-operative hospital contact [165], re-operation rates [166] [167]. learning curves [94] and the impact of high or low volume surgeons [168].

The Pelvic Floor Disorders Registry (PFDR) [169] was the national patient registry for the American Urogynaecological Society (AUGS). The data collection is currently closed while data is being analysed. The focus is on pelvic organ prolapse (POP) and evaluates effectiveness, quality of life and safety following surgical intervention and non-surgical management (pessary). It is web-based and collects provider and patient reported outcomes from patients under specialist and generalist care for prolapse. It does not include urinary incontinence but in comparison to the BSUG database it has the difference of including conservative measures of pessaries but is limited to prolapse conditions currently.

Limitations of databases

There is concern that databases can encourage a spirit of conservatism. A more complicated group of patients, high-risk cases and new techniques may lead to higher complication rates so these cases may be avoided. If some surgeons “cherry pick” their cases to ensure a low complication rate this firstly means the surgeon may appear more skilled than others and it disadvantages those high-risk patients who do not receive an operation. This requires complicated risk adjustment.

Personal communication (June 2017) with an orthopaedic surgeon with experience of working with an orthopaedic database suggested that clinicians have been suspected of altering their practice to improve their figures. The example given was that there was a penalty if a certain number of complete revisions were required, so some surgeons would perform a washout if there was infection, even though the optimal treatment would have been a complete revision, which is an example of when a database could cause harm to patients. This is an issue of probity and whether this was done consciously or subconsciously it would need to be addressed. The way this could be moderated would be to audit clinicians practice to ensure appropriate care was being given.

There can be controversies about who the data belongs to and how the data should be used and whether consent to provide the data can be withdrawn and data removed. This would be overcome if it was mandated by government.

Physicians can feel uneasy about publicly reporting their results from databases as they fear poor data quality and weak risk-adjustment algorithms. Such anxiety was felt

prior to the HQIP audit (personal communication with consultant involved May 2018), regarding the Consultant Outcome Publication project which required large scale collaboration. HQIP [147] an independent group worked with specialist societies to ensure that clinicians understood and were happy with the processes. Overall it was supported, and reservations were more about the quality and presentation of the data and the timescale involved. Clinicians generally welcomed the review of their practice and wanted any outcomes to be constructive rather than destructive and they recognised that it would be helpful with patient care.

The process of sharing and pooling results may provoke anxiety and fear of external scrutiny in some clinicians. Fear that outcomes will not be as good as their peers and an anxiety that they have 'let their patients down' and may fear the consequences. This is a legitimate concern, but, by definition, most clinicians will be found to be within the appropriate confidence limits or ranges of accepted outcomes. If clinicians are found to have variances in results, then this presents an opportunity to review practice and this may overall improve care and outcomes for women.

Comparison to other evidence

Evidence to inform medical decision making is derived from many different sources including computer modelling, cellular level experiments and studies on animal and human subjects and these are presented in different formats such as bench science papers, case series, case control studies, outcomes research, cohort studies, observational studies, randomised control studies and systematic reviews [170].

When RCTs are double blinded, well designed and appropriately analysed, they provide high levels of confidence in the outcome with respect to internal validity, particularly if subsequent studies can replicate them. However, they cannot always be applied to day-to-day clinical practice as they may lack external validity or ‘generalizability’ to larger populations due to unrepresentative healthcare providers and settings and atypical patients. Database analysis can complement evidence from RCTs to compare how information found in highly controlled trials translates to real life heterogenous clinical environments [171]. Databases allow realistic expectations of clinical practice to be reported.

Healthcare providers in trials often have a particular passion, expertise or skill for that area of study [172] and may be based at centres of excellence [173] so not represent the enthusiasm, skills or resources of a clinician at a non-specialist centre which would be represented in the heterogeneous skill mix seen in databases. Healthcare providers involved in RCTs must have equipoise and be willing to allow treatments for their patients to be allocated at random and this may not be acceptable to all clinicians, which may bias those providers involved in the RCT. An RCT would not be possible if clinicians were not willing to enter into them, such as happened with this topic, of SUI, in 1991 in North Thames region. Gynaecologists and urologists each thought their method of treating stress incontinence was the best and did not want to change their practice. There was "collective equipoise" but not "individual equipoise" so a trial could not be initiated [174].

Patients included in RCTs can be highly selective due to exclusion criteria, and poor recruitment rates. The resultant trial population may not represent the general

population [173] which leads to difficulties extrapolating the results to the heterogeneous comorbid populations seen by clinicians day to day [172]. This has been demonstrated in psychiatric trials where just under 2% of 36,000 schizophrenia patients and only 20% of psychiatric outpatients met common eligibility requirements for large RCTs relevant to their conditions [175, 176]. Depending on which patients are captured within the database, they are often more representative of the general population than those entered into RCTs. They tend to include wider ranges of age, BMI, ethnicity and socioeconomic status, they often have increased comorbidities, more severe disease and multiple medications, and socially more likely to be people in full-time employment, and those thought to be unlikely to observe treatment protocols [173]. Patients enrolled in trials must be prepared to have their treatment allocated on a random basis which can introduce bias in recruitment as this group of patients may differ from patients who do not want uncertainty [174].

The 'trial effect' can lead to patients in trials receiving better care due to intensive clinical supervision and enhanced follow up [172, 173], rarely seen in routine care, which can lead to more positive outcomes in both arms of the RCT compared to observing the intervention outside the RCT.

RCTs may not take into account the patients' beliefs and wishes and the clinicians' clinical acumen whereas databases maintain the integrity of the clinical context including the decision making process which is important in functional problems such as incontinence [174] rather than the RCT protocol determining the treatment. In a database, despite being governed by the same national guidelines, management strategies vary between clinicians, including planning care, pre-operative preparation

and operating techniques. There can be differences in how they counsel patients and in patient selection raising the possibility of bias. This lack of randomisation, when using data from a database, is a potential for bias, as the differences in outcomes seen may be due to the different composition of the treatment groups rather than differing efficacy of the intervention [177]. The characteristic of a patient that means they receive a certain treatment may indeed be the characteristic that alters the outcome, rather than the intervention. This bias can be obvious, which can be compensated for in the study design and analysis, but can also be hidden. The design of the database can overcome these problems.

Resources can be a constraint with all trials, and RCTs require adequate funding, time and enthusiasm [172]. RCTs can be expensive, take many years to develop, run and evaluate [178] so may lag behind clinical innovations with newer ideas, medicines, or surgical devices being developed before testing the previous one is completed. High costs and time constraints of RCTs can mean the RCT is not large enough or of a long enough time frame to identify infrequent adverse outcomes or detect harm. This can result in a reliance on surrogate markers that may not correlate well with the outcomes of interest [179]. Databases are generally lower cost than RCTs and once set up will continue to run.

RCTs are normally powered to detect clinical benefit, however there are less frequently power calculations to assess its ability to detect rare adverse events or those that have a long latency like malignancies or chronic pain [172]. As long as the database is appropriately set up in terms of timeframe and outcome collection, these are more likely to be detected due to greater numbers and longer term follow up [180].

Databases are more likely to detect adverse treatment effects that would not have been seen in the less comorbid patients included in RCTs. A database may be designed to answer research questions that traditional research may not answer as the numbers required make an RCT impractical or the timeframe makes the cost prohibitive. They can also be used to assess whether slight differences in practices, which would be impractical to set up a clinical trial for, produce a beneficial effect in patients.

Conclusion

Well designed, well supported databases have been shown to improve clinical care and patient safety by ensuring the quality of operating surgeons using benchmarking with adequate risk adjustment. They require investment by regulatory bodies to ensure they are fit for purpose. Linking databases to additional clinical information increases their utility, without increasing the burden of the clinician, however tighter regulations of GDPR laws may make this more of a challenge in the future.

The BSUG database differs from the cardiac database, as firstly it is not mandatory but secondly the outcomes are not as straightforward. The cardiac database measures mortality, which is binary and is easy to check via HES data for validation purposes. The orthopaedic database has similarities to BSUG with respect to device insertion, like the SUI mesh, as they also insert devices which are tracked and monitored. This came about due to concerns with the devices which is similar to the mesh situation faced by the urogynaecology community now. However there are alternative operations for SUI which means it is different to the orthopaedic registry.

The DUGAbase it the Danish equivalent urogynaecology database and has greater completion and is validated. There are differences in the laws on data collection in Denmark and the UK which previously restricted data collection like the DUGAbase in the UK. The National Consultant Information Programme (NCIP) [181] will now provide locally and nationally benchmarked data for individual consultants and is part of the Getting It Right First Time (GIRFT) programme which commenced in 2016. This provides data about consultants' activity and outcome data based on HES data. The outcomes currently are volume, length of stay or day case rate, mortality and the readmission rate which are not as detailed or specific as the BSUG database. Additionally the patterns of benign gynaecology care in English NHS Hospital Trusts identifies national indicators to provide an overview of benign gynaecology care in England [182].

The "real world" evidence from databases contributes to Comparative Effectiveness Research (CER). CER is "the generation and synthesis of evidence that compares the benefits and harms of alternative methods to prevent, diagnose, treat and monitor a clinical condition, or to improve the delivery of care [183]". It aims to improve health care at the individual and population levels by helping consumers, clinicians, purchasers, and policy makers to make informed decisions. It can identify clinical characteristics which will predict how successful different interventions will be in different patients.

This can also be useful when considering Value Based Health Care (VBHC) which describes health care that delivers the best possible outcomes to patients for the lowest possible cost [184]. If the value and cost of each intervention can be identified, then the STAR model (Socio-Technical Allocation of Resources) can be used [2]. It allows commissioners to allocate health resources to best benefit patients. Value triangles are used for each intervention which show a cost: benefit ratio. Visual representation (figure 17) can be created to show the comparative cost and value of each intervention. The green triangle shows a high value low cost intervention which offers the best Value Based healthcare (VBHC) whereas the red triangle offers the least value but a high cost, so has been left to the end in this treatment algorithm.

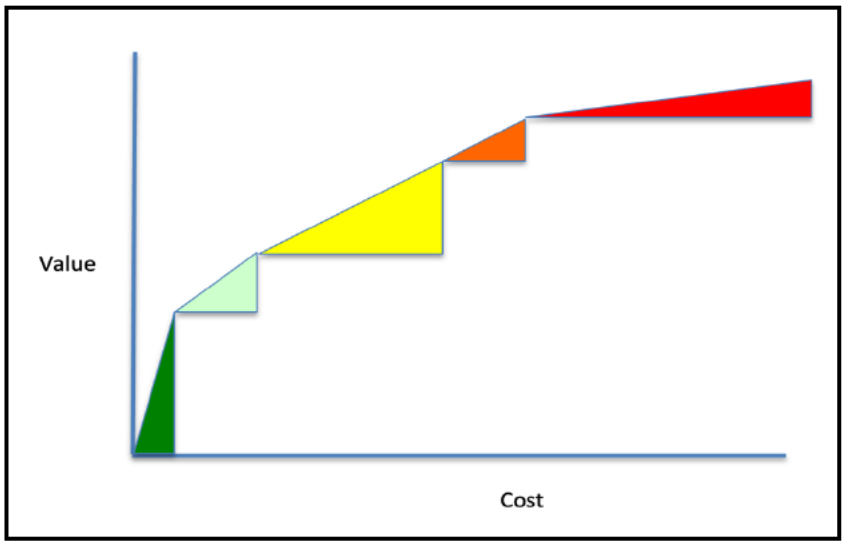


Figure 17: A visual representation of cost against value added: Value triangles [2]

Initial assessment of the potential uses of the BSUG database

From knowledge of the BSUG database from the website and personal clinical use, it was known to have strengths, but it was also known not to be a perfect database. There thus needed to be an assessment of whether it was possible to use the database for the aim of this thesis.

The strengths were that it was widely available to members of BSUG and had huge amounts of data entered already with over 12 years of use throughout the UK equating to >30,000 continence procedures. The data entered is real world data without strict inclusion or exclusion criteria. The weaknesses were that it was not 100% completed as it is not mandatory or validated. However, the amount of missing information was not known with regards to number of procedures entered compared to total number of procedures performed or with regards to the missing variables and outputs. This was thus an important question to be answered in this thesis. The information entered onto the database is not validated and patients may report their outcomes to the operating clinician meaning this may bias the results depending on the patients' thoughts towards the clinician. There was no knowledge as to clinicians' views of the database and any reservations as to its use. This again was an important area to try and be addressed in this thesis.

However, despite these potential biases, the strength of the amount of data held in the database made it worthy of analysis to explore the questions described below in the aims and objectives. Performing this exploration and analysis of the data within the BSUG database would also explore the potential biases (e.g. missing data, how data is recorded) and allow recommendations for how the database could be improved.

Hypothesis

The BSUG surgical database can be used to compare outcomes following common incontinence procedures and to identify patient characteristics that affect outcomes.

Aims

Overall aims:

- To use the BSUG database to explore:
    - outcomes and complications for different surgical procedures for SUI
    - the impact of different patient characteristics on outcomes and complications

- To assess the suitability of the current urogynaecology database by
    - Using experience gained from analysing the database including understanding the strengths and limitations of the BSUG database
    - Assessing how clinicians perceive existing databases using questionnaire to BSUG and IUGA members
    - Considering use of the BSUG database for a prognostic model

Methods used in the thesis

The BSUG database was used to assess outcomes for urinary incontinence in two analyses.

Primarily, solely RPT and PUB were analysed, as these were the most common procedures prior to the mesh pause when this work was started, to establish patient reported outcomes and the influence of age, BMI, urodynamics diagnosis, grade of operator and bladder injury, on outcomes and complications. This was achieved using Excel and STATA statistical programming independently by the author (see appendix 3). This work was performed during the initial year of the thesis and was presented at the first-year review. This has been published [185-187] and is documented in **chapter 2.** This was performed as a pilot of the BSUG database prior to embarking on further analysis.

The original long-term aim of this work had been to continue to analyse data related to RPT to assess the suitability of using the BSUG database to develop a prognostic model. However, during this period of work there was the national ban on mesh tapes, including RPT, being performed. It was clear the mesh pause would lead to a long delay in re-instatement of RPT and it was evident that the other procedures for SUI would become more important. Thus the planned analyses were adjusted as below.

Secondarily, a more in-depth analysis with a multivariable analysis to further explore utilising large datasets to include an even larger data set of RPT, PUB, AFS and colposuspension. The statistical work was performed by University of Birmingham statisticians. This is documented in **chapter 3.**

Clinicians in the UK and internationally, were questioned regarding their views about BSUG and international databases to determine reasons for non-compliance via questionnaires commissioned by BSUG and IUGA. The results were provided for this thesis and **Chapter 4** details themes generated from these answers.

Through this work, strengths and limitations of the BSUG database were identified and an assessment made of potential biases such as missing data. These are described in **chapter 5.**

Finally, throughout the thesis, the process of analysis was used to assess the suitability of the BSUG database, for the development of a prognostic model. This has allowed recommendations to be made for how the database could be improved and these are discussed in **chapter 5.**

Chapter 2: Pilot data analysis: Two procedures RPT & PUB

Background

The BSUG database holds information on a large number of procedures for stress urinary incontinence (SUI) and has previously been analysed on an ad hoc basis [136] but not regularly or on a large scale. Outcomes and complications of procedures for SUI surgery have been described in RCTs and observational studies as detailed in chapter one [59, 60, 64, 65, 68, 70, 71, 76, 77, 80, 82, 84, 85, 87, 89, 95, 97] and the Cochrane review [188], but none of these studies included the large number of participants, or timescales, that are recorded in the BSUG database.

The BSUG database records pre-operative patient characteristics including age, BMI, pelvic floor muscle training (PFMT), urodynamic diagnosis (UDS,) parity and previous continence surgery. Intra-operative information recorded includes concomitant surgery, anaesthetic, grade of operator, and intra-operative complications including bladder injury. Post-operative outcomes are recorded, and any post-operative complications are noted at follow up.

The first step in exploring the potential uses of the data within the BSUG database was to perform a pilot analysis of baseline data (patient characteristics, procedures performed), and pre-operative assessments.

As part of this, the clinical usage of urodynamic studies of clinicians entering data can be examined. As previously described, the VALUE and VUSIS trials [29-32] demonstrated that in certain populations UDS are not required prior to SUI surgery [30, 32, 189]. The use of pre-operative UDS is recorded within the BSUG database

and thus presents an opportunity to further understand the potential role of UDS in this setting in a broader population and to ascertain whether UDS are still routinely performed prior to SUI surgery.

Pre-determined post-operative outcomes are entered onto the database as described in Chapter 1. However, due to the lack of formal analyses using the BSUG database it is not clear how well these outcomes are recorded, how they are affected by missing data and thus which outcomes could be used in any statistical analysis. Complications are also recorded on the database such as bladder injury and the same exploration of the potential use of this data as per post-operative outcomes needs to be performed. Thus, an exploration of the complications recorded and how they are recorded was required. This would also allow exploration of whether any of these complications could be used as a benchmarking tool for surgery.

The second step was to perform a univariate analysis of potential pre-operative and intra-operative characteristics to determine whether the data could be used in this way and explore the potential limitations such as missing data or poor recording of data e.g. heterogeneity.

The pilot analysis commenced in December 2016 and at this time, RPT and PUB were the most performed procedures as this was prior to the mesh pause. Thus to maximise the number of data available for this pilot analysis the data obtained was restricted to participants undergoing these two procedures.

Aims

The aims of this retrospective cohort study were

- To compare pre-operative patient characteristics of patients undergoing RPT and PUB and
- To establish the use of UDS prior to SUI surgery
- To evaluate appropriate outcome measures
- To evaluate the outcomes of RPT and PUB using the measures identified
- To assess how complications of surgery were recorded in the database and summarise this data
- To assess bladder injury in particular as a surgical complication and explore the potential for this to be used as a benchmarking tool for surgical procedures for SUI
- To assess whether outcomes were influenced by different patient and operative characteristics
- To use the pilot analysis to understand how the data could be used for future research

Hypothesis

The BSUG surgical database can be used to assess outcomes of RPT and PUB and patient characteristics will be identified that alter those outcomes, meaning it is suitable for further study.

Methods

A retrospective cohort study was performed using female patients undergoing RPT or PUB from the BSUG database.

Population and intervention

The retropubic tape group included patients who underwent their first SUI surgery using RPT (Midurethral Sling-Tension free vaginal tape (MUS-TVT) (Ethicon Gynaecare, New Jersey), Advantage and Advantage Fit (Boston Scientific, Boston)) between 1st February 1999 to 27th January 2016.

The bulking agent group included patients who underwent either a primary or repeat PUB (Bulkamid and Macroplastique) from 1st February 1999 to a later date of 23rd December 2016 due to later data acquisition. Repeat PUB could be following any previous SUI surgery. If patients had two PUB procedures, then they could be included in the analysis twice as having a 'first surgery' and then again as having a 'repeat surgery' as it was an analysis of an individual surgical event with each operation being counted as a new 'case' and analysed independently.

Concomitant surgery (such as vaginal hysterectomy) was noted as a potential confounding factor when looking at complications, as the complication could have occurred from the non-SUI (concomitant) surgery.

Patient characteristics

The characteristics of patients undergoing the two procedures were compared to assess whether there may be differences in the types of patient that receives each treatment. The following characteristics were assessed; age, BMI, PFMT, UDS diagnosis, parity, previous SUI surgery for PUB, concomitant surgery (excluding simple procedures such as cystoscopy, laparoscopy and hysteroscopy), anaesthetic type and grade of operator. The utilisation of UDS over time were considered in view

of the recommendation from NICE [38] and evidence from trials published in 2012 to show non-inferiority of not performing UDS [30, 32, 189] for uncomplicated SUI prior to an operation.

The characteristics of the patient follow-up procedure were recorded e.g. timescale and method.

Patient reported outcome selection

Percentages of completed patient reported outcomes were established. The patient reported outcomes recorded and evaluated were PGII, change in SUI, change in OAB and ICIQ questionnaires as described below. Bladder injury was explored as a complication of surgery.

Primary outcome to describe outcome of procedure

The primary outcome of PGII [110], as described in chapter 1, was selected as the primary outcome based on previous literature [98, 105-108]. It was categorised into two groups. “Better” including very much better and much better and “not better” including little better, no change, little worse, much worse and very much worse [130].

Secondary outcomes

Secondary outcomes included change in SUI symptoms and change in OAB symptoms again as described in chapter 1. If a patient reported their SUI was “cured” or “improved” this was counted as success compared to “no change” or “worse”. OAB was divided into two groups: those patients with pre-operative OAB symptoms and those without. If patients had pre-operative OAB symptoms their options for reporting

would be “cured”, “improved”, “no change” or “worse” [128]. If they did not have pre-operative OAB symptoms their options would be “new symptom of OAB” or that “OAB had never been present”.

Bladder injury rate was calculated overall and per centre and a funnel plot created. This was assessed for its utility as a benchmarking tool. Reasons for variation were considered and perforation rates for different surgical operators and BMI calculated.

Additional secondary outcomes included other operative complications, return to theatre, return to hospital and readmission to hospital. The post-operative complications recorded were bladder, urethral, ureteric, bowel, vascular or neurological injury, blood loss >500ml, blood transfusion, peri-operative thromboembolism and death.

Variables to be explored

The variables recorded in the database to be explored as characteristics to assess impact on outcomes were: Age, BMI, PFMT, UDS, previous SUI surgery, grade of operator and bladder injury. These have previously been shown to affect outcomes [59-73, 75, 78, 79, 83, 86, 89, 96, 98-100, 102-104] and were available on the database.

Data acquisition

The data was acquired following a successful application to BSUG. The application was approved in a two-stage process initially by the BSUG Research Committee and subsequently ratified by the BSUG Database Committee thereby ensuring robust scrutiny for the application for release of information (see appendix 1). Anonymisation of data was performed prior to release to ensure individual patients, doctors and surgical centres could not be identified by the research team. Data was stored in accordance with University of Birmingham standards [190, 191].

Data were extracted from the database by the IT company (The IceWay: ICE ICT) and were received as Excel spreadsheets. Analysis and presentation of the data was performed using Excel (Microsoft, Redmond, WA) and Stata (StataCorp, College Station TX). A funnel plot was generated using standard methodology [192]. A Chi^2 Test was selected to compare groups. P-values <0.05 were considered statistically significant.

Statistics

STATA statistical analysis programming was learnt and performed by this author for this analysis. The reader is directed to appendix 3 to view the STATA do.file created and used in STATA to identify the information for each section of the results. This learning was achieved using the Stata handbook and attending a course. The excel spreadsheet from BSUG was uploaded into Stata and data analysed using the do.file. The column headings were altered to ensure they were distinct from each other as many of them started with the same few words. The variables were then coded into a

language that was compatible with Stata using ‘rename’, ‘encode’, ‘generate’ and ‘recode’ commands.

Mean and standard deviations were calculated for continuous variables when needed. Continuous variables were grouped into appropriate groups using ‘clonvar’, ‘recode’ ‘label define’ and ‘tab’ (appendix 3). Other variables were converted into binary groups to enable Chi^2 tests to be performed. The do.file can subsequently have any dataset in the same format uploaded into it to update the results after acquisition of further data.

Missing data

Missing data was defined as missing (not recorded), incomplete or invalid (i.e. entries outside the feasible range for that characteristic). For each variable the number of records with missing data was recorded and as a percentage of the total records. To account for missing data in subsequent univariable analyses pairwise deletion was used [193]. Details on missing data are shown on the relevant tables (tables 10, 12, 14-18) and in appendix 4.

Results

During the period 1st February 1999 to 27th January 2016 there were 18,763 primary RPT (all first procedures) recorded on the BSUG database and during the period 1st February 1999 to 23rd December 2016 there were 1386 PUB procedures: 783 primary and 539 repeat (64 unclear).

Summary data is presented below. All original data and outputs can be found in appendix 4 with the corresponding data files for STATA in appendix 3.

Patient characteristics

Data was recorded and summarised for the following patient characteristics: age (yrs), BMI (kg/m^2), PFMT (recorded as "offered - yes/no" and if offered as "accepted - yes/no"), UDS performed [(yes/no) and if performed the diagnosis was recorded], parity (could not be reported) and previous urogynaecological surgery for SUI (yes/no) (Table 10).

For age, there was a skewed normal distribution (figure 18 and 19). The mean age of patients undergoing RPT was 52.3 years (median 50) and 59.4 years for PUB (median 61). There were younger mean ages for primary PUB (mean 57.9, median 57) compared to repeat PUB (mean 61.5, median 62).

For BMI, there was a mean value of 28.9 kg/m^2 for RPT and 30 kg/m^2 for PUB again with a skewed normal distribution (figure 20 and 21).

Pelvic floor muscle training (PFMT) was recorded to be offered to 91.4% of participants (n=15085) undergoing RPT and 85.1% (n=963) for PUB. Of those it was offered to, 96.4% accepted in both groups. 8.6% of RPT and 14.9% PUB were recorded as not having been offered PFMT.

Urodynamics (UDS) was performed in 96.6% (n=17097) of those undergoing RPT and 95.3% (n=1194) for PUB, however the result was not recorded in 693 RPT and 41 PUB. UDS were recorded as not being done in 601 (3.4%) patients prior to RPT and 59 (4.7%) patients prior to PUB. There was a wide range of urodynamic diagnoses seen in patients undergoing both procedures and these are summarised in figure 22. Of those patients who did have a urodynamic result recorded, the commonest diagnosis on UDS for both RPT and PUB was urodynamic stress incontinence (USI) (77.2% (n=12655) & 67.0% (n=773) respectively). There was a lower percentage of mixed and voiding dysfunction in RPT compared to PUB (mixed: 15.6% vs 21.7% and USI + voiding dysfunction: 2.5% vs 4.9%) whereas RPT were proportionately more popular in the pure USI group.

Parity was only entered onto the database after June 2011 therefore was not included.

Only primary RPT were retrieved from the database. All PUB were retrieved, with 1322 recording information on previous SUI surgery. 783 (59.2%) were primary procedures and 539 (40.8%) patients had undergone previous procedures for SUI. 350 (64.9%) patients had had one previous procedure, 85 (15.8%) two previous procedures and 20 (3.7%) three, with incomplete data on 84 patients.

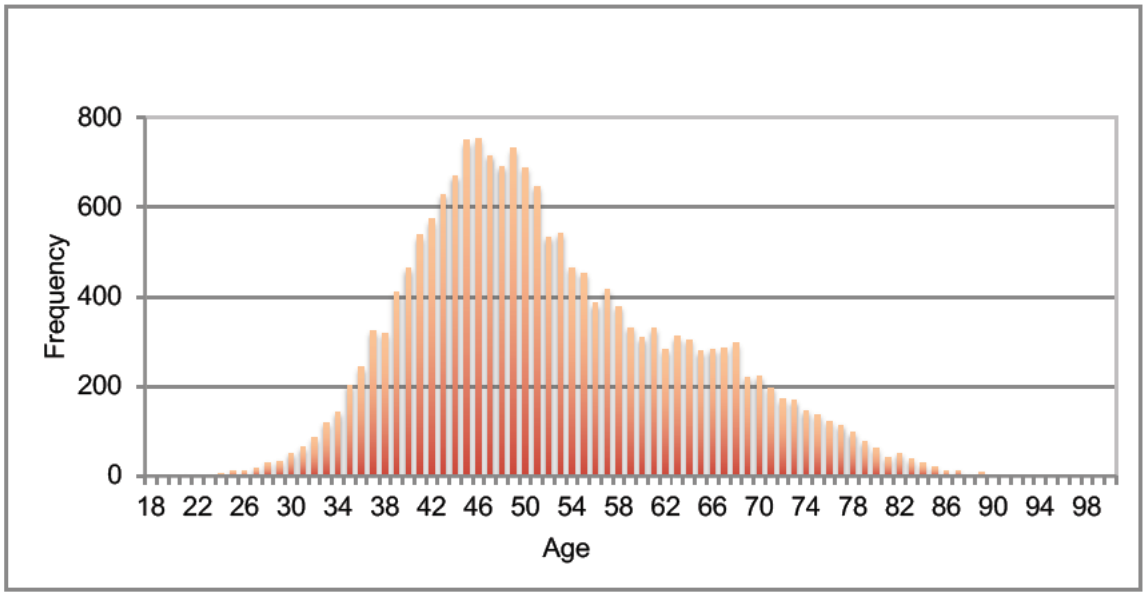


Figure 18: Age distribution of patients undergoing RPT for SUI on the BSUG database [(n=18,231), missing data (n=532, 3%)]

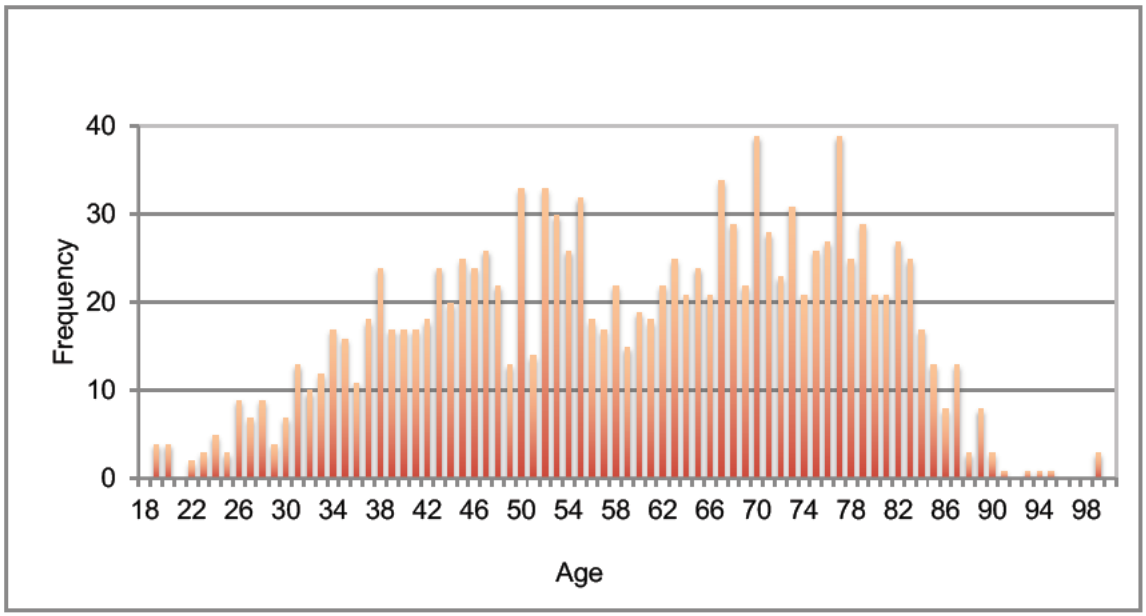


Figure 19: Age distribution of all patients (primary and repeat) undergoing PUB for SUI on the BSUG database [(n=1330), missing data (n=56, 4%)]

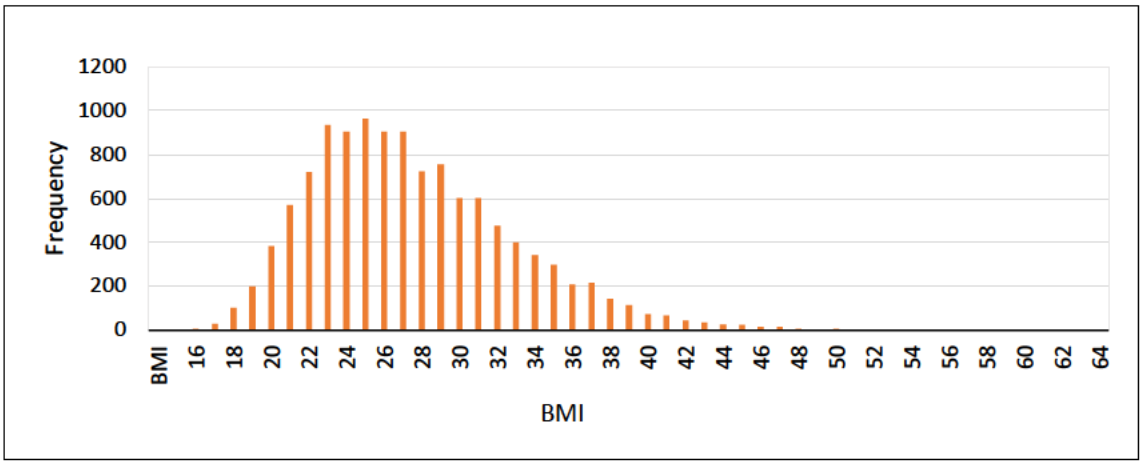


Figure 20: BMI distribution of patients undergoing RPT for SUI on the BSUG database [(n=11858), missing data (n=6904, 36.8%)]

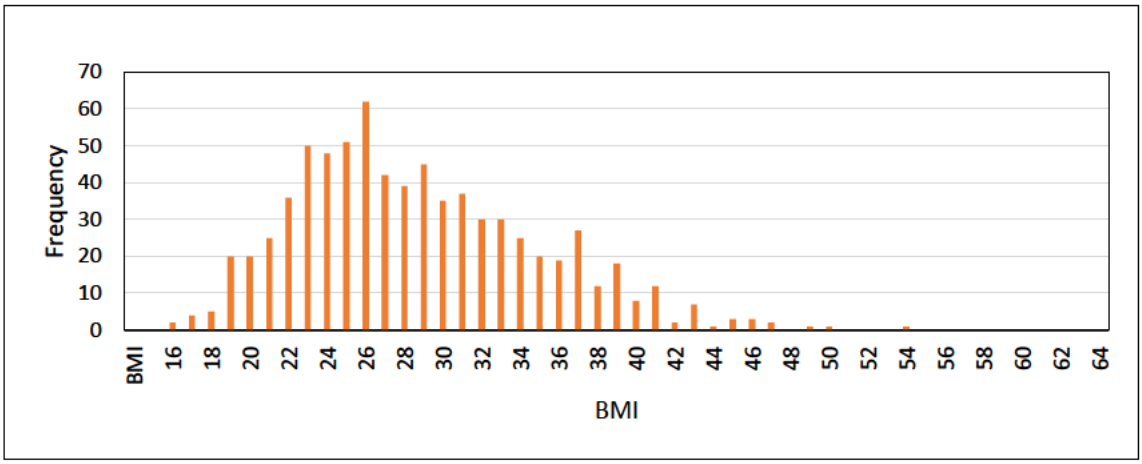


Figure 21: BMI distribution of all patients (primary and repeat) undergoing PUB for SUI on the BSUG database [(n=743), missing data (n=643, 46.4%)]

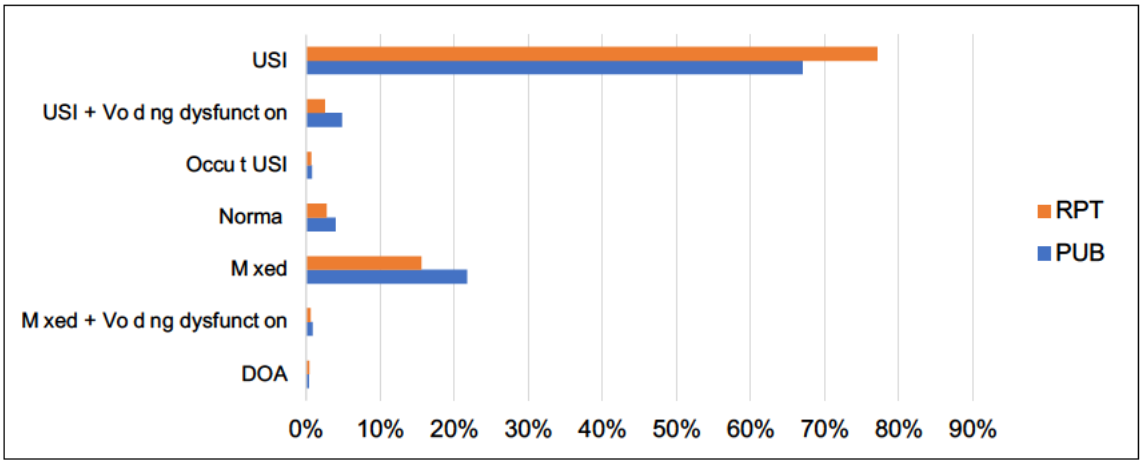


Figure 22: Distribution of diagnoses on urodynamics (UDS) for patients undergoing RPT and PUB on the BSUG database (RPT n=16404 PUB n=1153]

Urodynamic utilisation on the BSUG database

The percentage of patients undergoing UDS remained similar from 2011 compared to 2015, which is before and after the VALUE and VUSIS [29-32] were published which showed that UDS did not improve outcomes in patients with symptoms of SUI (Table 9).

Date	UDS	No UDS	Unanswered
2011 and earlier (n=8781)	92.4%	2.8%	4.8%
2012-2013 (n=5344)	90.3%	3.7%	5.9%
2014 (n=2548)	89.3%	3.6%	7.1%
2015 (n=2016)	90.3%	3.3%	6.4%

Table 9: Comparison of percentage of patients undergoing UDS prior to RPT pre 2011 to subsequent years on the BSUG database

Procedure	Retropubic tape (RPT) n=18763			Periurethral Bulking (PUB) n=1386			Both
	Number with data recorded (n)	Missing data (n,%)	Result (% of those with recorded data)	Number (n)	Missing data RPT (n,%)	Result	Reason for missing data
Age (years)	18231	532 (2.8%)	52.3 yrs mean (median 50, range 18-100)	1330	56 (4%)	59.4 years mean (median 61, range 19-99)	No age recorded or age <18 or >100
Body mass index (BMI) kg/m²	11859	6904 (36.8%)	Mean 28.9	743	643 (46.4%)	Mean 30	BMI not recorded or invalid entry BMI<15 or >65
Pelvic floor muscle training offered (yes/no/offered but declined) (PFMT)	16510	2253 (12%)	Offered n=15085 (91.4%);not offered n=1425 (8.6%); Of those offered n=14535 accepted (96.4%) and n=550 declined (3.6%)	1131	255 (18.4%)	Offered n=963 (85.1%); not offered n=168 (14.9%). Of those offered n=929 accepted (96.4%) and n=34 declined (3.5%)	Not recorded
Urodynamics (UDS) recorded as being performed ("yes/no")	17698	1065 (5.7%)	Stated performed in 17097 (96.7%) (but no recorded result in 693); Not performed in n=601 (3.4%)	1253	133 (9.6%)	Stated performed in 1194 (95.3%) (but no recorded results in 41); Not performed in n=59 (4.7%)	Not recorded
Commonest Urodynamics (UDS) diagnosis if performed	16404	-	Urodynamic stress incontinence n=12655 (77.2%)	1153	-	Urodynamic stress incontinence n=773 (67.0%)	-
Parity*	Not possible						
Previous surgery for stress urinary incontinence (SUI)	Na	Na	All RPT were primary procedures	1322	64 (4.6%)	783 (59.2%) first procedure; 539 (40.8%) undergone one or more procedure for SUI	Not recorded

Table 10: Patient characteristics recorded in BSUG database for patients undergoing a retropubic tape or periurethral bulking procedure (1999-2016). (Appendix 4 table 1-6)

**Parity was only entered after June 2011 and thus analysis was not possible*

Operative characteristics and intraoperative complications

Data was recorded and summarised for the following operative characteristics: concomitant surgery performed, anaesthetic used, grade of operator and complications (Table 12).

Of patients undergoing RPT, n=4535 had concomitant surgery and 83 of PUB had concomitant surgery performed. Table 11 details the types of surgery performed and the numbers.

Concomitant surgery	RPT	PUB		Concomitant surgery	RPT	PUB
AR	958	6		Manchester Repair	16	
PR	1216			AR + Manchester Repair	2	
AR + PR	716	4		PR + Manchester Repair	2	
VH	80			AR + PR + Manchester Repair	8	
VH + AR	303			Laparoscopic Hysterectomy	30	
VH + PR	48			TAH	42	
VH + AR + PR	368			Botulinum	12	17
Colpocleisis	16	2		STARR	5	
SSF	13			Fenton's	31	
AR + SSF	17			Vaginal Mesh	125	2
PR + SSF	34			Lap SCP	18	
AR + PR + SSF	35	3		Open SCP	34	
VH + SSF	4			Lap SHP	10	1
AR + VH + SSF	5			Open SHP	3	
AR + PR + VH + SSF	25			Other - combinations	179	2

Table 11: Concomitant surgery recorded to be performed at the same time as RPT and PUB on the BSUG database

4355 patients had a concomitant surgery performed. (Simple procedures excluded – cystoscopy, laparoscopy, hysteroscopy etc). AR – anterior repair, PR posterior repair, VH vaginal hysterectomy, SSF sacrospinous fixation, TAH total abdominal hysterectomy, STARR stapled transanal rectal resection, SCP sacrocolpopexy, SHP sacrohysteropexy.

The most common anaesthetic for RPT (concomitant and no concomitant surgery included) was general anaesthetic (70.2%) with local anaesthetic with sedation (13.7%) and spinal (13.1%) next common, and others being local or a combination of GA and regional anaesthesia. For PUB the most common was general anaesthetic (65.2%) then local anaesthetic (24.8%) and local anaesthetic with sedation (6.2%).

When looking at grade of operator for RPT, 77.5% of procedures were performed by consultants with specialty trainees performing 13.8% and subspecialty trainees performing 6.2%. For PUB a higher percentage of procedures were performed by consultants (85.6%) with a similar percentage of subspecialty trainees (6.1%) but lower percentage of specialty trainees (6.3%) (figure 23).

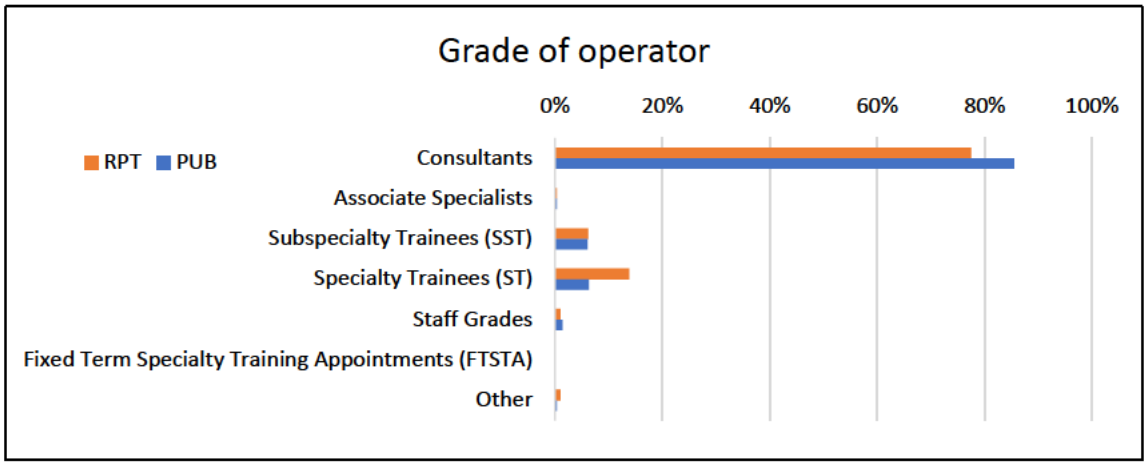


Figure 23: Grade of operator displayed as percentage of cases performed for RPT (n=18499) and PUB 9 (n=1356)

Data was recorded and summarised for intra-operative bladder perforation during RPT. 18,494 (98.6%) records contained data regarding bladder perforation (269 missing) during RPT to give a perforation rate of 3.5% (n=639). If all those missing data were assumed to be negative the rate would be 3.41% but if they were all presumed to have a perforation, the rate would be 4.8%. For all future analyses in this chapter, a decision was made to use 3.5% as the expected rate.

Procedure	Retropubic tape (RPT) n=18763				Periurethral Bulking (PUB) n=1386			Both
	Number with data recorded (n)	Missing data (n,%)	Result (% of those with recorded data)		Number (n)	Missing data RPT (n,%)	Result	Reason for missing data
Operative characteristics								
Concomitant surgery performed (yes/no)	17044	1719 (9.1%)	4355 yes; 12689 no		1056	330 (23.8%)	83 yes; 973 no.	Not recorded
Anaesthetic used for all RPT surgeries (general/local, local with sedation, spinal, other*)	18438	325 (1.7%)	General n=12945(70.2%); local n=74 (0.4%); local with sedation n=2526 (13.7%); spinal n=2412 (13.1%); other n= 481 (2.6%)		1353	33 (2.4%)	General n=882 (65.2%); Local n=336 (24.8%); Local with sedation n=84 (6.2%); Spinal n=36 (2.7%); Other n=15 (1.1%)	Not recorded
Grade of operator for surgery [Consultant/subspecialty trainee (SST)/specialty trainee/other^]	18499	264 (1.4%)	Consultant n=14334 (77.5%); SST n=1147 (6.2%); specialty trainee n=2556 (13.8%); other n=462 (2.5%)		1356	30 (2.2%)	Consultant n=1160 (85.6%); SST n=83 (6.1%); specialty trainee n=86 (6.3%); other n=27 (2%).	Not recorded
Intra-operative complications								
Bladder perforation (all surgeries RPT) (yes/no)	18494	269 (1.4%)	Yes n=639 (3.5%); no n=17855 (96.5%)		NA	NA	NA	NA

** other includes general anaesthetic and spinal; general and epidural; general and caudal; caudal only*
^other includes Associate specialists, staff grades, fixed term speciality training appointments and other

Table 12: Operative characteristics recorded in BSUG database for patients undergoing a retropubic tape or periurethral bulking procedure (1999-2016). (Appendix 4 tables 7-9)

Data was also recorded and summarised for other intra-operative complications when the surgery performed did not include concomitant surgery (Table 13). There were no major intraoperative complications recorded during 973 PUB procedures when performed without concomitant surgery, compared to the following complications for the 12,689 RPT without concomitant surgery.

	N (%)
Blood loss > 500ml	50 (0.4%)
Vaginal Button-holing	42 (0.54%)
Peri-operative blood transfusion	7 (0.06%)
Urethral injury	11 (0.14%)
Vascular injury	6 (0.05%)
Peri-op VTE	3 (0.03%)
Neurological injury	1 (0.01%)
Bowel injury	1 (0.01%)
Death	1 (0.01%)

Table 13: Other complications for RPT with no concomitant surgery (variable missing data – for denominator see appendix 4 table 11)

The frequency of these complications was low and thus, even with such a large data set, no trends were able to be established.

Follow-up and outcomes

Data was recorded and summarised for the following: timing and method of follow-up, patient reported outcome measure used and outcomes summarised as PGII, patient reported changes in SUI and OAB symptoms (Table 14).

For RPT, there was an even spread of patients seen at 6 weeks (33.9%), 3 months (34.5%) and 6 months (28.1%) with the most common modality being by outpatient visit (79.2%). For PUB, the commonest follow up time was 3 months (56%) with 35% at 6 weeks and 9% at 6-12 months. The majority of follow up was via an outpatient visit to the operating surgeon's clinic (95%) and 4% telephone follow up.

Selection of Patient Reported Outcome Measures

For RPT, PGII was completed in 60.6% (11366/18763) of procedures, change in SUI (56.9% 10685/18763), change in OAB (54.8% 10290/18763) with the completion rates of the post operative ICIQ questionnaires being much lower: ICIQ-UI (25.2% 4731/18763), ICIQ-VS (11.7%2194/18763), ICIQ-SM (10.1% 1904/18763), ICIQ-LUTS (4.2% 787/18763) and ICIQ-OAB (1.4% 256/18763).

For PUB, PGII was completed in 53.5% (742/1386), change in SUI 47.9% (664/1386) and change in OAB 44.9% (623/1386). The ICIQ questionnaires were completed in the following: ICIQ-UI (9.0% 125/1386), ICIQ-VS (1.0% 14/1386), ICIQ-SM (0.7% 10/1386), ICIQ-LUTS (2.3% 32/1386) and ICIQ-OAB (1.2% 16/1386).

PGII, change in SUI and change in OAB were selected for use as patient reported outcomes due to previous literature [98, 105-108, 110, 128], and ICIQ questionnaires were therefore not used in further analysis.

Procedure	Retropubic tape (RPT) n=18763				Periurethral Bulking (PUB) n=1386			Both
	Number with data recorded (n)	Missing data (n,%)	Result (% of those with recorded data)		Number (n)	Missing data RPT (n,%)	Result	Reason for missing data
Follow up and outcome measures								
Follow-up time	11984	6779 (36.1%)	6 weeks n=4057 (33.9%); 3 months n=4137 (34.5%); 6 months n=3363 (28.1%); 12 months n=427 (3.5%)		756	630 (45.5%)	6 weeks n=267 (35.3%); 3 months n=420 (55.6%); 6 months n=56 (7.4%); 12 months n=13 (1.7%)	Not recorded
Follow-up method	12213	6550 (34.9%)	Outpatients n=9676 (79.2%); postal questionnaire n=1356 (11.1%); telephone n=1068 (8.7%); GP n=84 (0.7%); Online n=12 (0.1%); Other n=17 (0.2%);		766	620 (44.7%)	Outpatients n=731 (95.4%); postal questionnaire n=1 (0.1%); telephone n=31 (4%); GP n=2 (0.3%); Online n=1 (0.1%);	Not recorded
Patient reported outcome measure (PROM) used	18763	Na	11366 (60.6%) PGII; change in SUI 10685 56.9%; change in OAB 10290 54.8%; post-operative ICIQ [ICIQ-UI 4731 25.2%] ICIQ-VS [2194 11.7%], ICIQ-SM [1904; 10.1%]; ICIQ-LUTS [787; 4.2%]; ICIQ-OAB [256; 1.4%] NB denominator is n=18763 as more than one measure could be used		1386	na	PGII 53.5% (742), change in SUI 47.9% (664), change in OAB 44.9% (623). Post operative ICIQ-UI (9.0% 125), ICIQ-VS (1.0% 14), ICIQ-SM (0.7% 10), ICIQ-LUTS (2.3% 32) and ICIQ-OAB (1.2% 16).	NA

PGII – Patient Global Impression of Improvement of Incontinence; OAB overactive bladder ICIQ – International consultation on incontinence questionnaire, -UI urinary incontinence, -VS vaginal symptoms – LUTS lower urinary tract symptoms

Table 14: Follow-up and outcome measures recorded in BSUG database for patients undergoing a retropubic tape or periurethral bulking procedure (1999-2016)

Outcomes reported using Patient Reported Outcome Measures

Patient Global Impression of Improvement of Incontinence (PGII)

91.0% of patients reported feeling better using the PGII following RPT (combining very much better with much better) compared to a significantly lower percentage of 59.2% for PUB (p =<0.01). There were no differences between primary and repeat bulking. Figure 24 demonstrates all the symptom categories.

Patient reported changes in SUI symptoms

A significantly greater percentage of patients reported their SUI cured following RPT (77.6%) compared to PUB (28.5%) (p<0.01). Similarly, a significantly greater percentage of patients found cure or improvement of their SUI symptoms following RPT (94.5%) compared to PUB (74.3%) (p<0.01). There were no differences between primary and repeat bulking. Figure 25 demonstrates all the symptom categories.

Patient reported changes in OAB symptoms

In RPT patients *with* pre-operative OAB symptoms, 26.3% reported cure of OAB symptoms, 38.7% reported improvement, 25.3% reported no change and 9.7% reported worsening. For PUB 7.5% reported cure, 31.2% improved, 55.5% no change and 5.8% worse (figure 26).

In those patients *without* pre-operative OAB symptoms, 9.7% of patients who had a RPT (396/4066) developed OAB as a *new* symptom compared to a significantly lower percentage of 2.4% who had a PUB (5/210) (p<0.01).

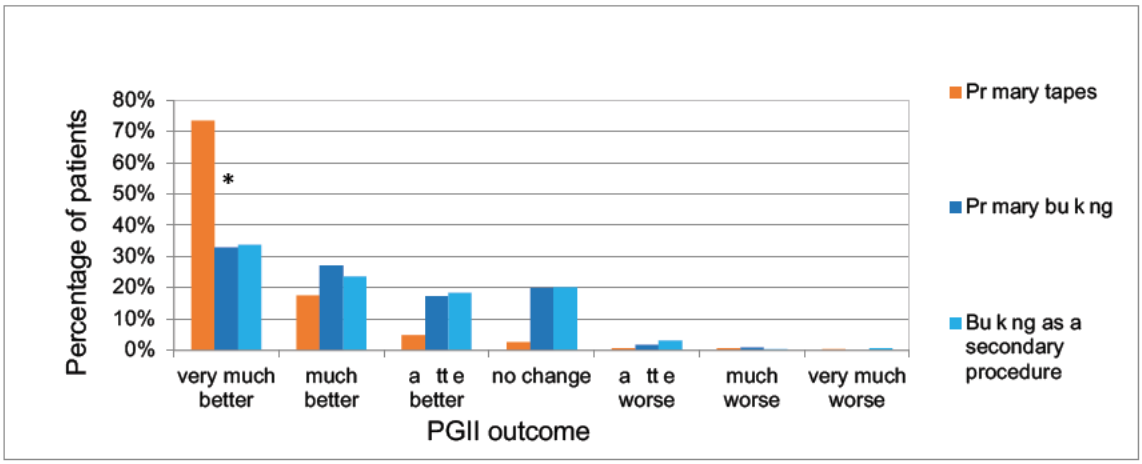


Figure 24: PGII: Outcomes reported using the Patient Global Impression of improvement scale for patients undergoing retropubic tapes and periurethral bulking (including primary v repeat procedures) (RPT n=11366 PUB n = 742) (Table 15).

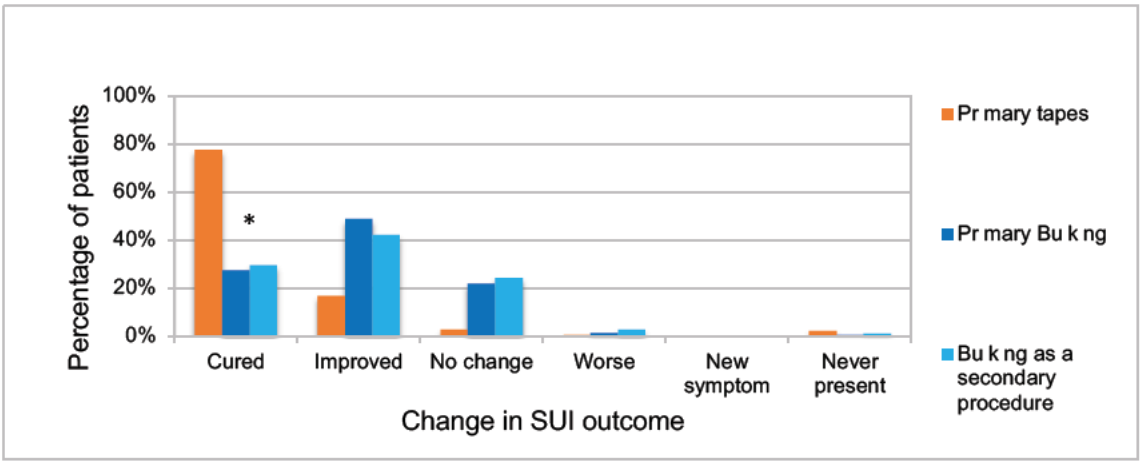


Figure 25: SUI: Outcomes reported by patients related to change in stress urinary incontinence (SUI) for patients undergoing retropubic tapes and periurethral bulking (including primary v repeat procedures) (RPT n = 10685 PUB n = 664) (Table 15)

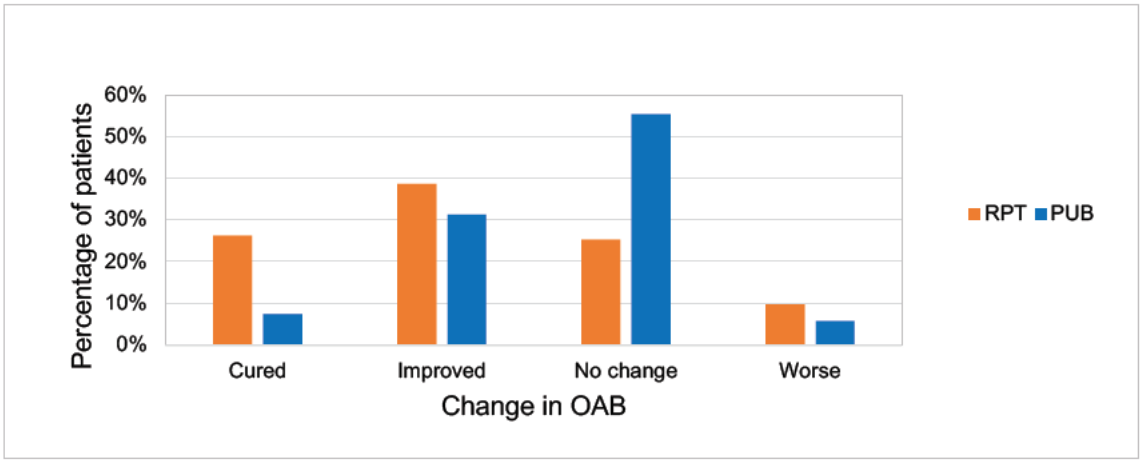


Figure 26: OAB: Outcomes reported by patients related to change in overactive bladder (OAB) for patients with *pre-operative symptoms undergoing retropubic tapes and periurethral bulking (including primary v repeat procedures). (RPT n = 6224 PUB n = 413) (Table 15)*

Procedure	Retropubic tape (RPT) n=18763				Periurethral Bulking (PUB) n=1386			Both
	Number with data recorded (n)	Missing data (n,%)	Result (% of those with recorded data)		Number (n)	Missing data RPT (n,%)	Result	Reason for missing data
Patient reported outcomes								
PGII	11366	7397 (39.4%)	Better (VMB&MB) 10339; 90.1%		742	644 (46.5%)	Better (VMB&MB) 439; 59.2%	Not recorded
Patient reported changes in SUI symptoms	10685	8078 (43.1%)	Cured n=8288 (77.6%); cure or improvement n=10096 (94.5%)		664	722 (52.1%)	Cured 28.5%; cured or improvement 74.3%	Not recorded
Patient reported change in OAB symptoms	10290	8473 (45.2%)			623	763 (55.1%)		Not recorded
Changes in OAB symptoms in those *with* pre-operative symptoms	6224	-	Cured n=1635 (26.3%); Improved n=2408 (38.7%); no change n=1573 (25.3%); worse n=608 (9.7%)		413	-	Cured n=31 (7.5%); Improved n = 129 (31.2%); No change n=229 (55.5%); Worse n=24 (5.8%)	
Changes in OAB symptoms in those *without* pre-operative symptoms	4066	-	OAB as a new symptom n=396 (9.7%); OAB never present n=3670 (90.3%)		210	-	OAB as a new symptom n=5 (2.4%); OAB never present n=205 (97.6%)	

PGII – Patient Global Impression of Improvement of Incontinence; OAB overactive bladder

Table 15: Patient reported outcomes recorded in BSUG database for patients undergoing a retropubic tape or periurethral bulking procedure (1999-2016). (Appendix 4 tables 12-21)

Postoperative complications

Data was recorded and summarised for the following postoperative complications: return to theatres for procedure related event within 72 hours, return to hospital within 30 days of surgery and readmission to hospital (Table 16). This analysis was restricted to patients who did not undergo concomitant surgery.

53 out of 8729 (0.61%) patients who had RPT without concomitant surgery are reported to have needed to return to theatre within 72 hrs compared to 1 out of 574 (0.17%) following a PUB (non-significant).

There is a lot of missing data regarding patients requiring return to hospital within 30 days with only 719/12698 of procedures performed without concomitant surgery having an answer for RPT. 8% (58/719) following a RPT were reported to have required to return to hospital within 30 days compared to 5/183 for PUB. This was a significant difference (p0.01) but in view of the missing data this must be viewed with caution.

Significantly more patients (368/8560 4.3%) following RPT required readmission to hospital than PUB (5/552 0.91%) (P<0.01).

Procedure	Retropubic tape (RPT) n=18763 Non-concomitant surgery n=12689				Periurethral Bulking (PUB) n=1386 Non-concomitant surgery n=973			Both
	Number with data recorded (n)	Missing data (n,%)	Result (% of those with recorded data)		Number (n)	Missing data RPT (n,%)	Result	Reason for missing data
Postoperative complications								
Return to theatre for procedure related event in 72 hrs~ (yes/no)	8729	3960 (31.2%)	Yes n=53 (0.6%); no n=8676 (99.4%)		574	399 (41.0%)	Yes 1 (0.17%) No n=573 (99.8%)	Not recorded
Return to hospital within 30 days of surgery (yes/no)*	719	11970 (94.3%)	Yes n=58 (8.1%) No n=661 (91.9%)		183	790 (81.2%)	5 yes (2.7%); 178 no (97.3%).	Not recorded
Readmission to hospital (yes/no)$	8560	4129 (32.5%)	368 yes (4.3%); 8192 no (95.7%)		552	421 (43.3%)	5 yes (0.91%); 547 no (99.1%)	Not recorded

~ when recorded reasons for return to theatre for RPT were active bleeding (n=3), drainage of haematoma (n=2), bowel injury (n=0), bladder injury (n=1), ureteric injury (n=0), voiding difficulty (n=2), emergency laparotomy for retropubic haematoma (n=1), removal of transvaginal tape (n=2) and loosening of transvaginal tape (n=1).

** when recorded reasons for return to hospital after RPT were trial without catheter (n=33), voiding difficulty (n=6). infection (n=3), active bleeding (n=2), haematoma (n=2).*

$ when recorded reasons for readmission to hospital after RPT were trial without catheter (4), voiding difficulty (2), infection (2), haematoma (2)

Table 16: Postoperative complications recorded in BSUG database for patients undergoing a retropubic tape or periurethral bulking procedure (1999-2016). (Appendix 4 tables 22-25)

Impact of variables on outcomes: patient characteristics

Effect of Age on RPT and PUB

For RPT, as age increased, the percentage of "better" on PGII and "cured" on change in SUI decreased (figures 27 and 28). In patients *with* pre-operative OAB there was no pattern seen following RPT related to age. In patients *without* pre-operative OAB, there was a higher percentage of new OAB following RPT with increasing age (figures 29 and 30).

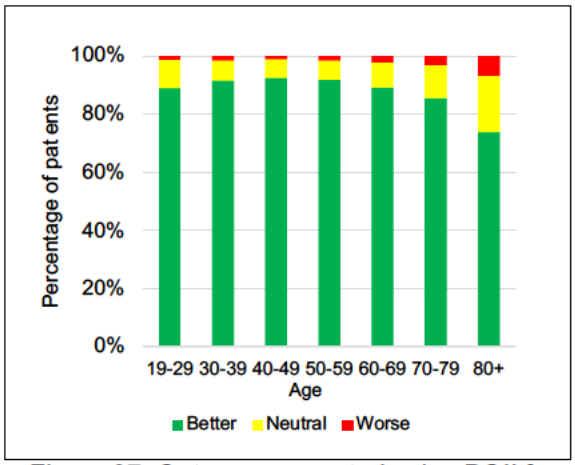


Figure 27: Outcomes reported using PGII for patients undergoing RPT, by age (n=11021)

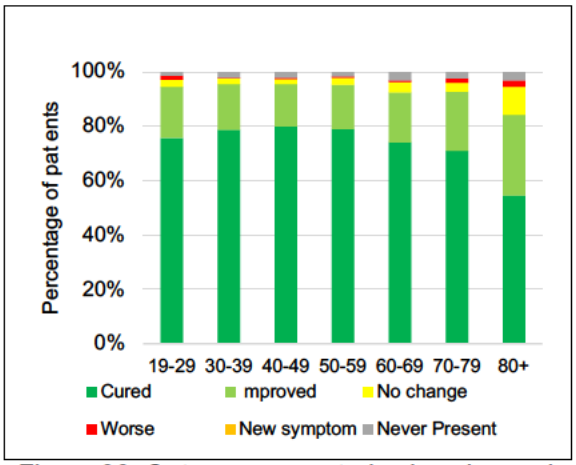


Figure 28: Outcomes reported using change in SUI for patients undergoing RPT, by age (n=10475)

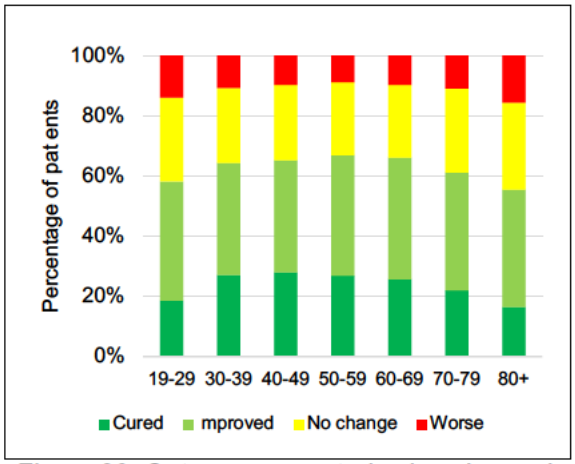


Figure 29: Outcomes reported using change in OAB for patients with *pre-operative OAB undergoing RPT, by age (n=6107)*

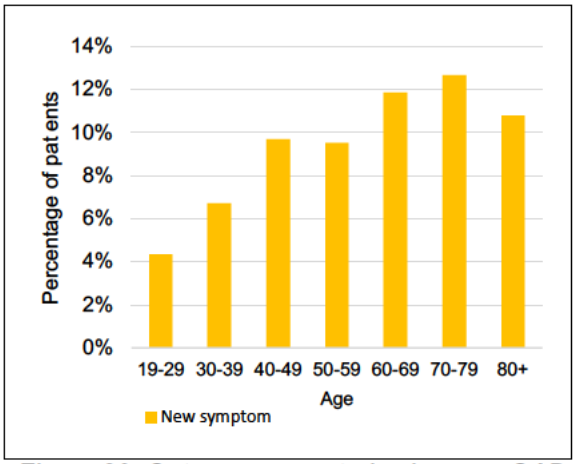


Figure 30: Outcomes reported using new OAB for patients without *pre-operative OAB undergoing RPT, by age (n=3986)*

For PUB, there is no change in outcomes of PGII, SUI and OAB with respect to age (appendix 4 table 30-33). There was not enough data for new cases of OAB with PUB with only 5 cases of new OAB following PUB.

Effect of BMI on RPT and PUB

Analyses were performed assessing the relationship between each of the characteristics and BMI. The full data is shown in appendix 4 for age, pre-op urodynamic diagnosis, grade of operator and anaesthetic use.

Each BMI group was similar in spread of age (n=11,596).

Change in UDS with BMI

As BMI increased the percentage of women with mixed results on pre-operative urodynamic studies (UDS) significantly increased ($p<0.05$ *) with a decrease in simple USI (figure 31).

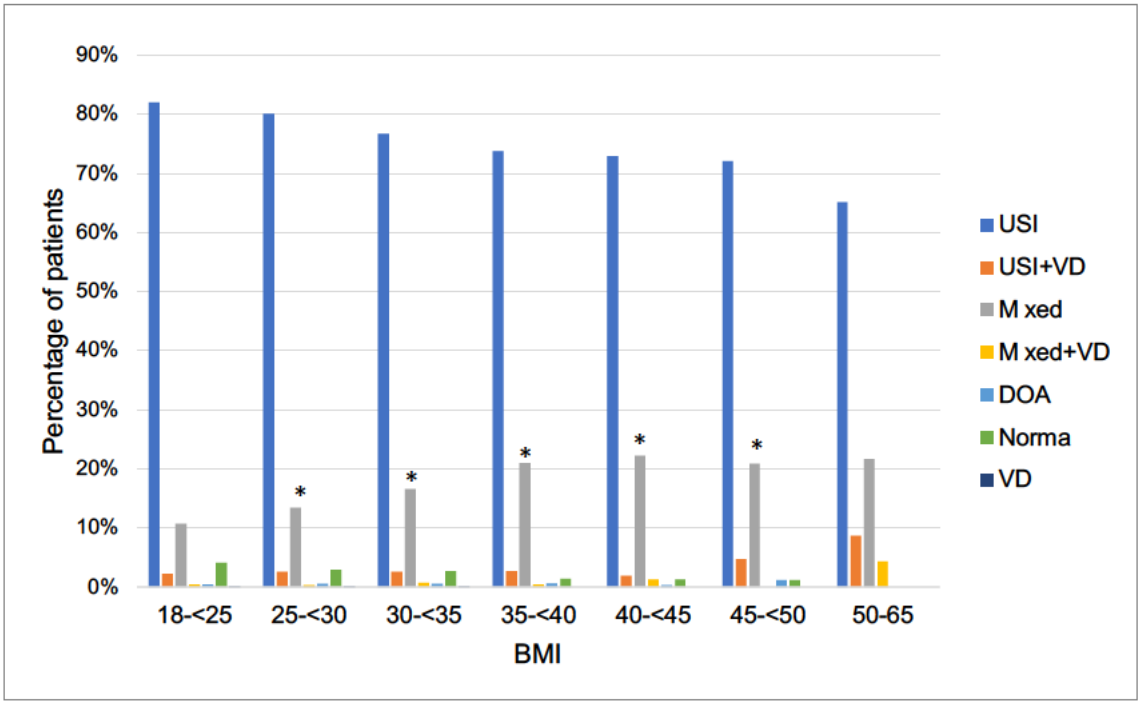


Figure 31: Distribution of diagnosis on urodynamics (UDS) by BMI for retropubic tapes (RPT) in the BSUG database (n=10,982). (appendix 4 tables 35-42)

OAB symptoms at presentation patients by BMI

Symptoms of OAB are related to BMI. Pre-operative OAB symptoms were significantly more common in women with increasing BMI (figure 32) ($p<0.05$ *).

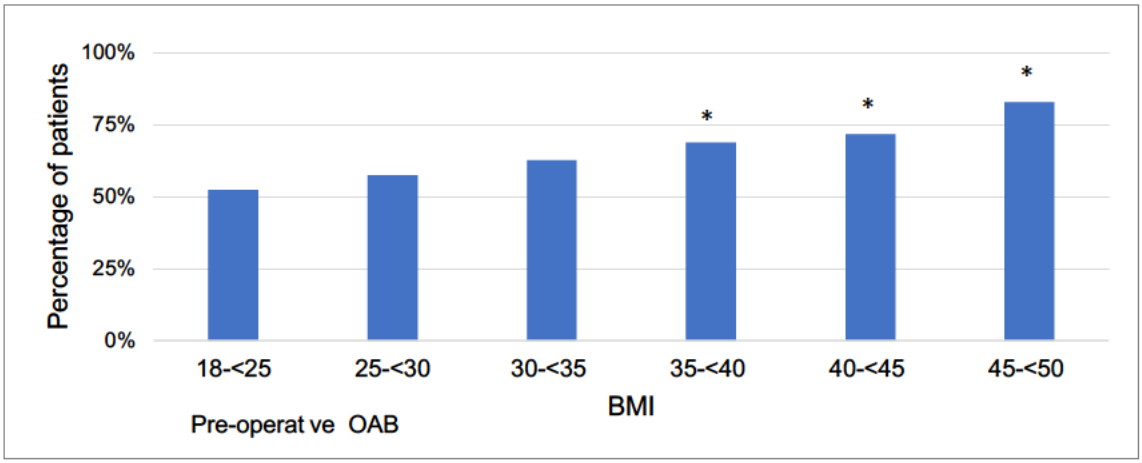


Figure 32: Percentage of Patients with *pre-operative OAB symptoms at presentation by BMI for RPT and PUB combined from the BSUG database (n=7505). (appendix 4 table 43)*

Grade of operator and BMI

The proportion of procedures performed by each grade in each bracket of BMI remained consistent until above BMI 40 where the proportions performed by consultants increased (figure 33).

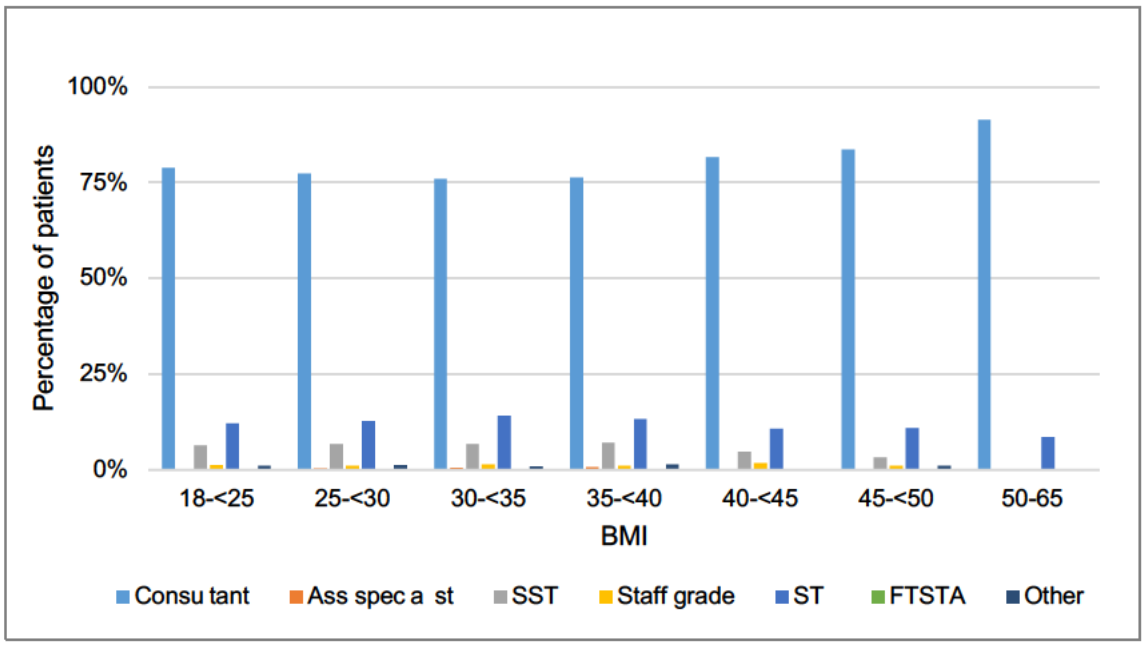


Figure 33: Percentage of patients operated on by each grade of operator by BMI for RPT (n=11748). (appendix 4 table 44)

There was no variation in the choice of anaesthetic for RPT with change in BMI category (appendix 4 table 45).

As BMI increases, positive outcomes for RPT as assessed by PGII declines, with a significantly greater success rate of 91.6% in the group of patients with a normal (18 - <25) BMI compared to 87.7 - 72% in the groups of patients with BMI >30 ($p<0.001$ *) (figure 34).

The percentage of patients reporting cure or improvement of SUI symptoms decreases with rising BMI. 97% of women with a normal BMI, state they were cured/improved compared to lower rates in women in higher BMI groups (94%-84%) ($p<0.005$ *) (figure 35).

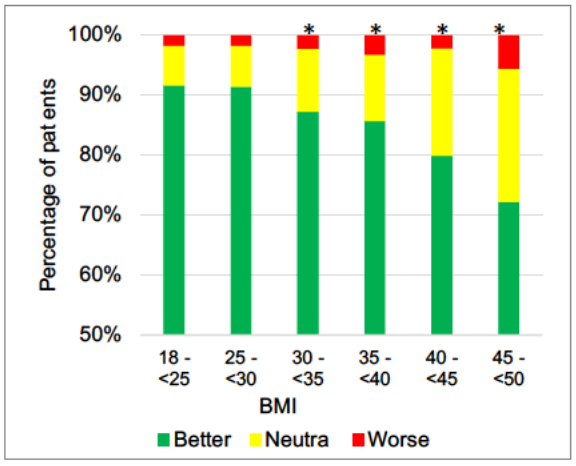


Figure 34: Outcomes reported using PGII for patients undergoing RPT, by BMI (n=7429). (appendix 4 tables 46-51)

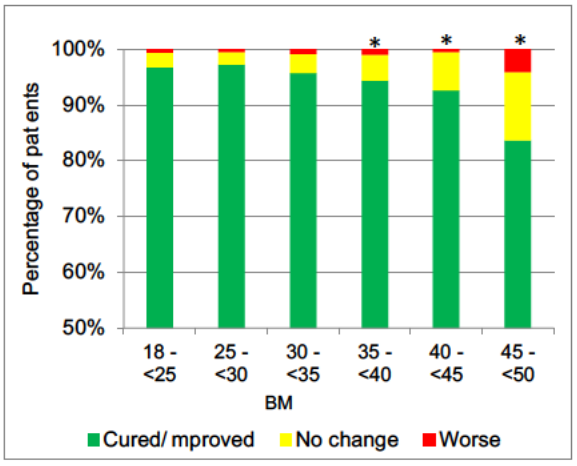


Figure 35: Outcomes reported using change in SUI for patients undergoing RPT, by BMI (n=7197) (appendix 4 tables 52-57)

BMI and changes in OAB symptoms reported by patients following RPT

Patient reported outcomes for change in *overactive bladder* symptoms show that as BMI increases, there are higher rates of patients reporting worsening post-operative symptoms ($p<0.05$). The graph is divided into BMI and outcome of OAB. As the BMI increases the percentage of 'worse OAB symptoms' increases and the percentage of OAB 'never present' decreases (figure 36).

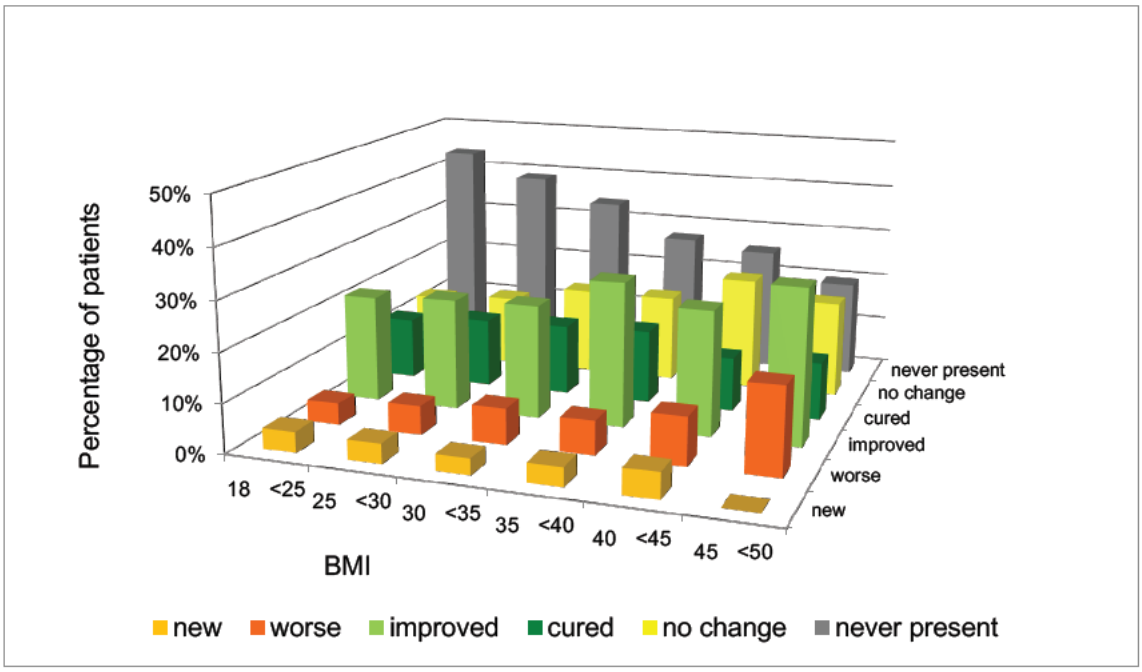


Figure 36: Outcomes reported using change in OAB symptoms for patients undergoing RPT, by BMI (n=7123) (appendix 4 table 58)

When considering patients *with* pre-operative OAB symptoms, a higher BMI led to a higher percentage of 'worse OAB' symptoms post RPT. For the group BMI 18-25, 8.45% become worse vs 65.8% being cured/improved compared to the group BMI 45-50 where 21.9% became worse vs 53.7% being cured/improved. The ratio of patients experiencing worsening of their OAB symptoms (when experienced pre-operatively) compared to being cured/improved increases with increasing BMI (figure 37) and is significant once BMI is over 40 ($p<0.05$ *).

In patients with *no* pre-operative OAB symptoms, the percentage of patients with de novo OAB was greater with increased BMI to a significant degree in the BMI group 40-<45 ($p<0.05$ *). There were no new cases of OAB in the group BMI 45-50 which does not fit with the pattern, but this may be because there were only 10 cases for analysis for this group as the majority of patients (N = 41) had pre-operative symptoms, which excluded them from this sub analysis (figure 38).

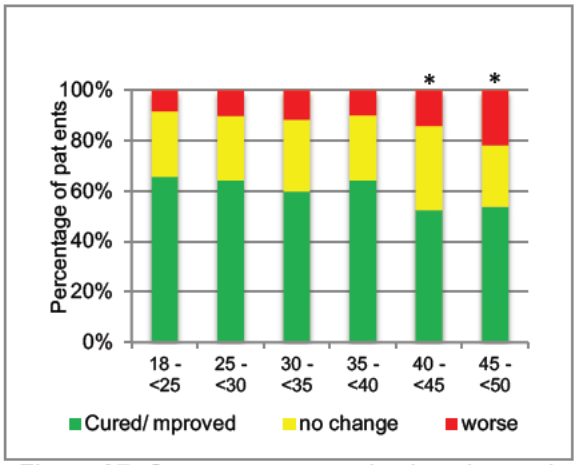


Figure 37: Outcomes reported using change in OAB for patients with *pre-operative OAB undergoing RPT, by BMI (n=4187). (appendix 4 tables 59-64)*

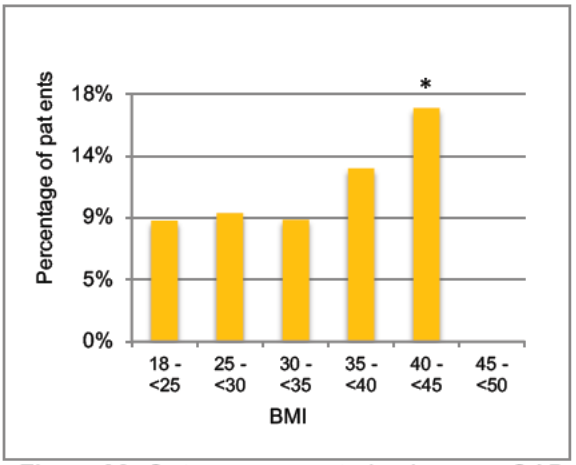


Figure 38: Outcomes reported using new OAB for patients without *pre-operative OAB undergoing RPT, by BMI (n=2936). (appendix 4 tables 65-69)*

There were no significant differences in the outcomes of PUB with differing BMI assessed by either PGII, change in SUI symptoms or change in OAB (appendix 4, tables 70-77).

Effect of PFMT on RPT and PUB

There was no effect of PFMT on outcomes for RPT or PUB (appendix 4 tables 78-83).

Effect of Urodynamic diagnosis on RPT and PUB

For RPT, patients characterised as having "USI" and "normal UDS" had the highest proportions of positive outcomes for PGII (92%, 89.9%). When comparing those with "USI" to those patients with any element of DO on their UDS ("Mixed" and "DOA") significantly more positive outcomes for PGII were seen with USI (92% for USI and normal UDS vs 86% for USI and any DO) ($p<0.05$) (figure 39). DO on UDS had the lowest percentage reporting a positive PGII (78.8%) and the highest percentage of patients reporting an adverse "worse" outcome on PGII (4.3%).

For RPT, patients with USI report cure of SUI symptoms in 78.3%, improvement in 16.2%, totalling 94.5% with positive outcome and 2.5% no change and 0.5% worse. The diagnosis with the highest percentage of improvement/cure of SUI was "normal" UDS (96.4%). The lowest SUI cure rates were in those patients with DO (66.7%) and DO combined with voiding dysfunction (62.3%) (figure 40).

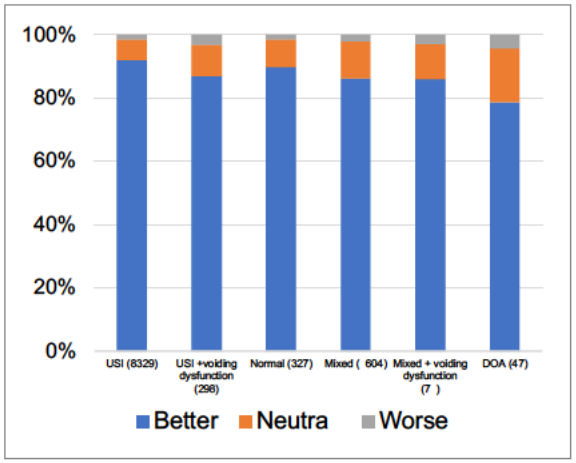


Figure 39: Outcomes reported using PGII for patients undergoing RPT, by UDS (n=10681). (appendix 4 tables 84-87)

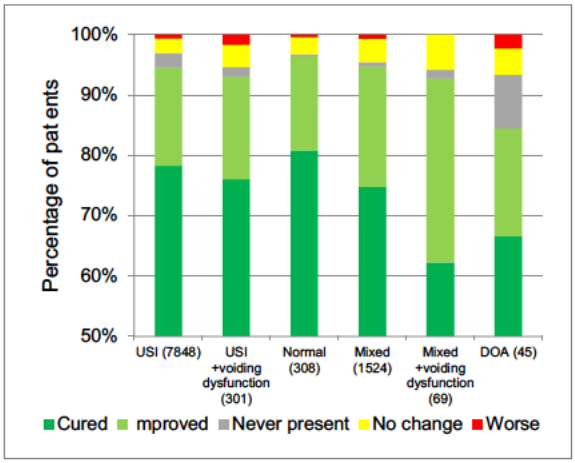


Figure 40: Outcomes reported using change in SUI for patients undergoing RPT, by UDS (n=10099). (appendix 4 table 88)

For RPT, there were no trends seen for change in OAB symptoms with respect to UDS (appendix 4 figure 89-91).

Three percent of patients did not undergo UDS prior to RPT. For those who did not have UDS, 95% felt better, 4.6% no change and 0.4% worse compared to 92% better, 6.4% no change and 1.6% worse with USI on UDS. There were no significant differences between positive outcomes of PGII for patients with USI on UDS and those that did not undergo UDS (p=0.59).

For PUB, primary and repeat surgeries were combined due to smaller numbers. PUB had a lower rate of success for PGII and SUI than RPT and this was true with all UDS diagnoses. Rates of success for PGII were 61.7% with USI, 65.7% with USI + voiding dysfunction and lower with a normal UDS (46.2%) and any DO (54.9%) on UDS. For SUI symptoms for PUB, a similar picture was seen as RPT with USI and with USI + voiding dysfunction, showing a slightly higher cure/improvement percentage than normal or DO. It was not possible to identify any patterns for OAB outcomes related to PUB (appendix 4 tables 92 + 94).

Effect of Grade of operator on RPT and PUB

No significant differences with regards to success rates measured by PGII or cure/improvement of SUI were found when comparing trainees to consultants for RPT. There was a higher percentage of patients that required return to theatre when a non-consultant grade (1.3%) compared to a consultant grade (0.5%) was the operator for RPT (p<0.01) (appendix 4 table 95-99, 101).

There were not enough numbers of trainees performing PUB to establish any differences in outcomes related to grade of surgeon for this procedure (appendix 4 table 100).

Effect of bladder perforation on RPT

When comparing outcomes assessed via PGII in n=11204, 91.0% patients felt "better" with no perforation compared to 89.2% who were affected by a perforation (P >.05) (appendix 4 table 102-103). Thus there did not appear to be an effect of bladder perforation on outcome as assessed by PGII.

When assessing SUI outcomes reported by patients (n=10401) following RPT complicated by a bladder perforation, 96.7% patients reported their SUI was cured/improved compared to 93.9% who had suffered a bladder perforation (P 0.006) (appendix 4 table 104-105) suggesting bladder perforation led to reduced success.

Effect of repeat surgery on PUB

There was a similar efficacy between PUB being performed as the primary surgery or after a previous procedure for SUI with no difference in the PGII (p = 0.47) or change in SUI outcome when looking at those patients that were cured (p = 0.57) or cured/improved (p = 0.21) (appendix 4 tables 117-120).

Procedure	RPT										
	PGII			SUI			OAB				
							Change		New		
	Number with data recorded (n)	Effect on outcome	Missing data n (%)	Number with data recorded (n)	Effect on outcome	Missing data n (%)	Number with data recorded (n)	Effect on outcome	Number with data recorded (n)	Effect on outcome	Missing data n (%)
Age	11021	Worse with increased age	41.3%	10475	Worse with increased age	44.2%	6107	No difference	3986	Increased with increased age	46.2%
BMI	7429	Worse with increased BMI >30 (p<0.05)	60.4%	7197	Worse with increased BMI >35 (p<0.05)	61.1%	4187	No difference	2936	Increased with increased BMI 40-45 (p<0.05)	62.0%
PFMT	10483	No change	44.1%	9786	No change	47.8%	9485	No difference	Na	Na	49.4%
UDS	10681	Worse with DO (p<0.05)	43.1%	10099	Worse with DO	46.2%	5958/9734	Worse with DO	3776	Nil	48.5%
Bladder perforation	11204	No difference	40.3%	10401	Worse with bladder perforation (p 0.006)	44.6%	Na	Na	Na	Na	Na
Grade of operator	11255	No difference	40.0%	10686	No difference	43.0%	6165	No difference	4026	No difference	8572 45.7%

Table 17: to show how patient and surgical characteristics affected outcomes of RPT from the BSUG database

Procedure	PUB										
	PGII			SUI			OAB				
							Change		New		
	Number with data recorded (n)	Effect on outcome	Missing data n (%)	Number with data recorded (n)	Effect on outcome	Missing data n (%)	Number with data recorded (n)	Effect on outcome	Number with data recorded (n)	Effect on outcome	Missing data n (%)
Age	717	No difference	48%	645	No difference	53.5%	400	No difference	207	No difference	56.2%
BMI	429	No difference	69%	401	No difference	71.1%	263	Too little data	119	Too little data	72.4%
PFMT	645	No difference	53.5%	567	No difference	59.1%	530	No difference	Na	na	61.8%
UDS	634	No difference	54.3%	571	No difference	58.9%	535	No difference	Na	Na	61.4%
Grade of operator	Not enough trainees performing bulking in this cohort										
Repeat surgery	713	No difference	48.6%	636	No difference	54.1%	na	na	na	na	na

Table 18: to show how patient and surgical characteristics affected outcomes of PUB from the BSUG database

Exploration of bladder perforation

Further analysis was undertaken to assess the relationship of different characteristics with bladder perforation rates and to see whether bladder perforation could be used as a quality measure (benchmarking tool) for centres. As stated previously a baseline perforation rate of 3.5% for RPT was used. Characteristics studied were BMI and grade of operator.

Bladder perforation during RPT and BMI

Data was initially studied using the binary category of BMI <25 and BMI ≥25. Perforation rates for women with BMI of under 25 were 4.6% while those with a BMI of 25 or more had a significantly lower ($p < 0.001$) perforation rate of 2.8% (appendix 4 table 106).

Subsequently data was analysed in categories of BMI and compared to normal BMI of 18-<25. A u-shaped curve was seen (figure 41) when comparing BMI and perforation rate thus demonstrating higher rates of perforation at the low and high extremes of BMI. There are significantly fewer perforations with the groups 25-<30 ($p=0.032$), 30-<35 ($p<0.001$), 35-<40 ($p<0.001$) compared to 18-<25, although interestingly this difference was not observed in the highest BMI groups with BMI 40-45 ($p=0.057$) and 45-50 ($p=0.54$). This may represent the lower numbers within these categories (appendix 4 tables 107-116).

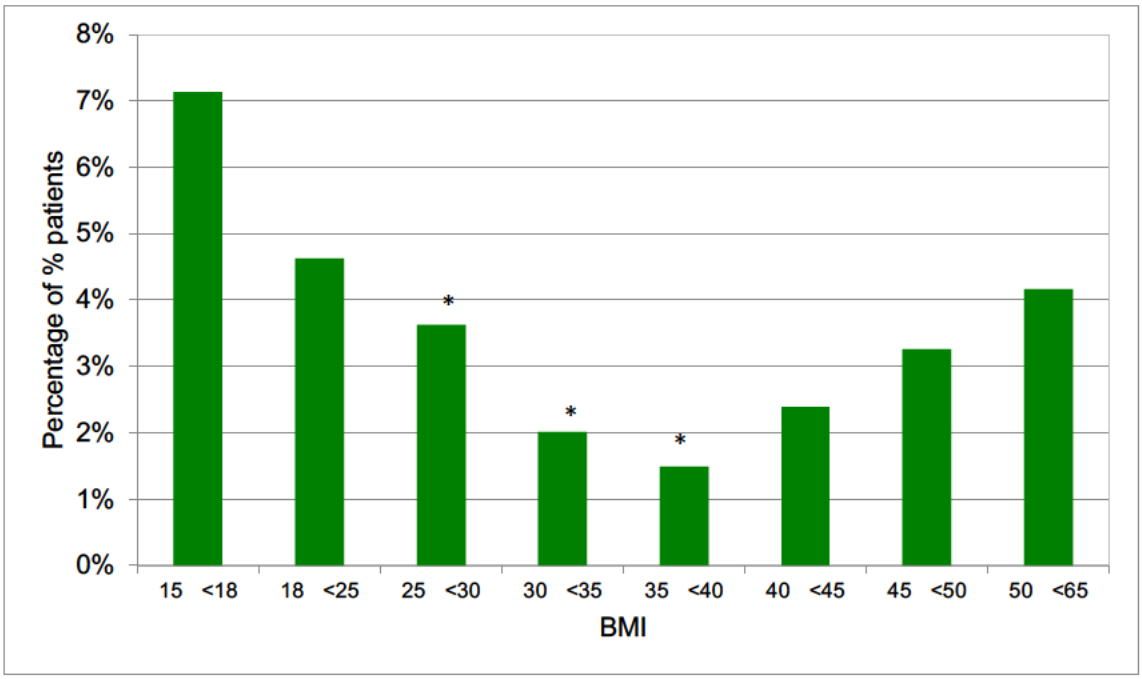


Figure 41 Bladder perforation rate (percentage) during RPT by BMI (n=11830)

Bladder perforation during RPT and grade of operator

Perforation rates according to grade of surgeon (figure 42) show the grade with the highest perforation rate was the specialty trainees (8.9%) followed by the staff grades (8.0%). Subspecialty trainees had a rate of 5.4% with consultants and associate specialists having the lowest rates of 2.2% and 1.6% respectively. A significantly greater perforation rate was seen in trainees (SST + ST) compared to consultants ($p<0.05$) (appendix 4 table 115 + 116). For the whole BSUG dataset: 4338 (23.5%) of cases were performed by *non*-consultant grade surgeons yet these accounted for 326 (51%) of the perforations.

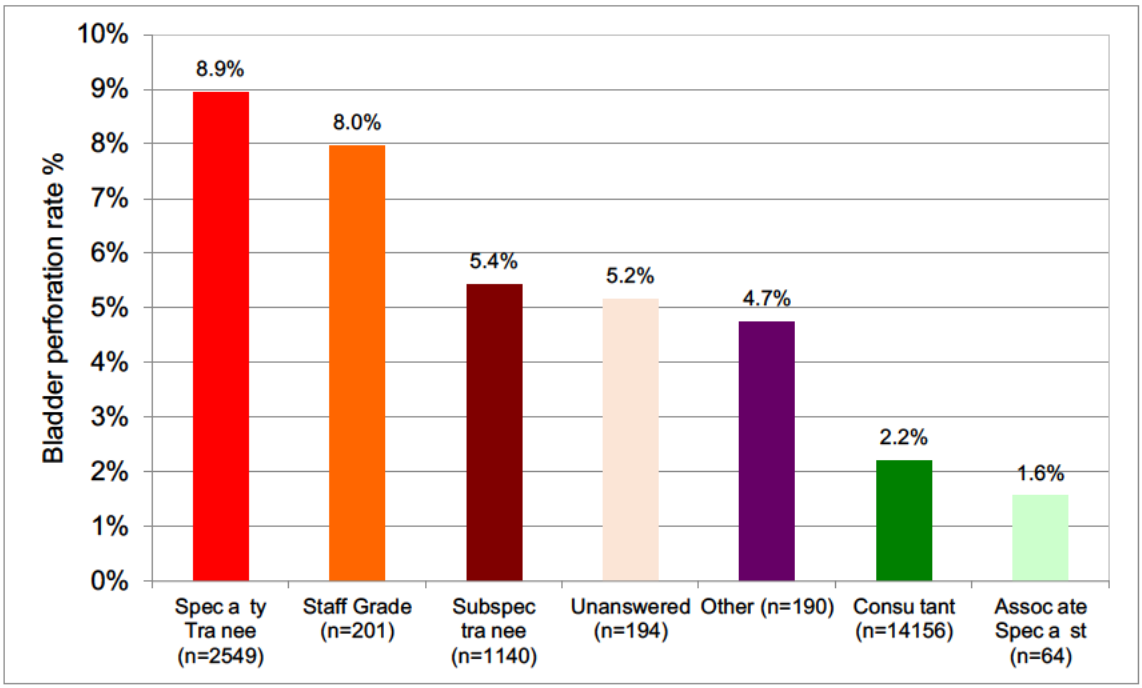


Figure 42: Bladder perforation rate (percentage) during RPT by grade of surgeon (n=18494)

Using perforation rates as a benchmarking tool for centres

A funnel plot (figure 43) to compare the perforation rates of different centres, shows bladder perforation rate per centre against numbers of cases entered per centre and illustrates how a benchmarking tool could appear. The benchmark perforation rate of 3.5% is marked on the figure with upper and lower control limits as shown. The limits represent +/- 3 standard error.

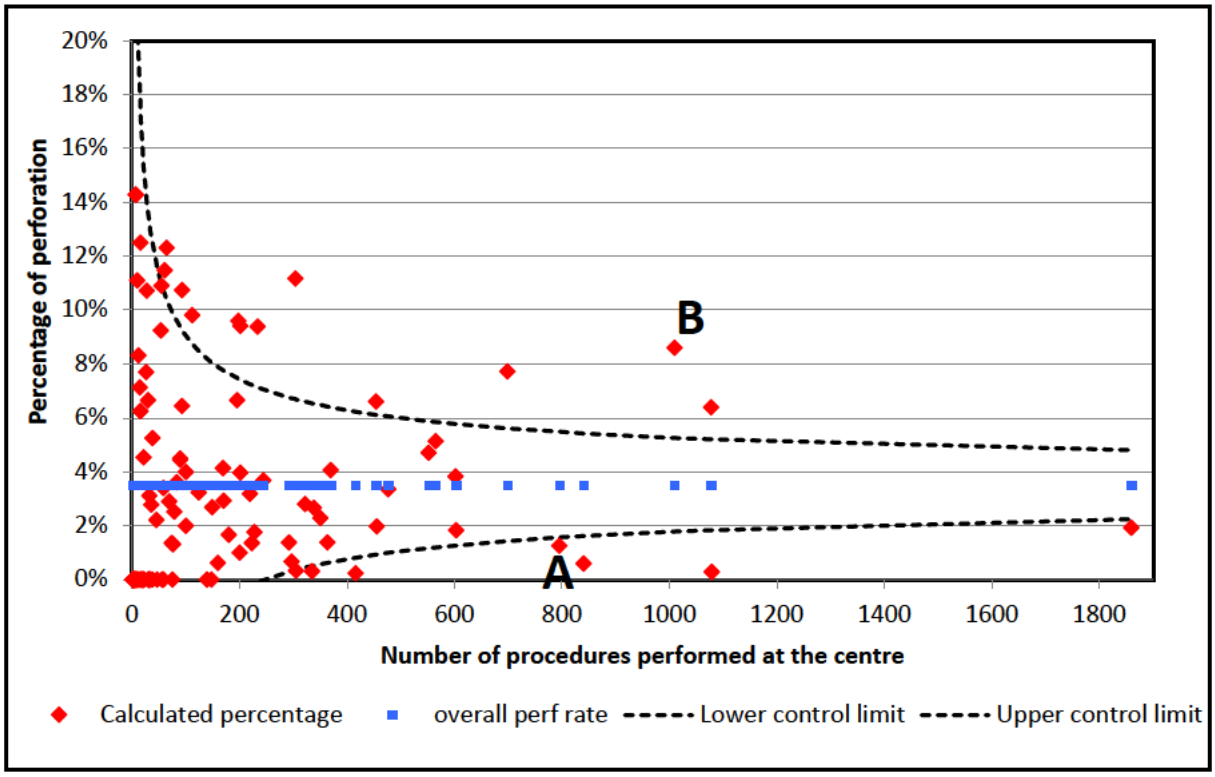


Figure 43: Funnel plot of % bladder perforation: Centres A & B marked

To investigate whether there was an effect of grade of surgeon at the different centres an analysis was performed assessing two centres with different perforation rates. Centre A, identified as a low outlier, with a perforation rate of 1.3%, had only 4.5% non-consultant grade surgeons (Figure 44) compared to centre B, identified as a high outlier, with 45.3% non-consultant grade surgeons resulting in a perforation rate of 8.5%. A similar finding was seen in other high and low perforation rate centres (figure 45 and 46).

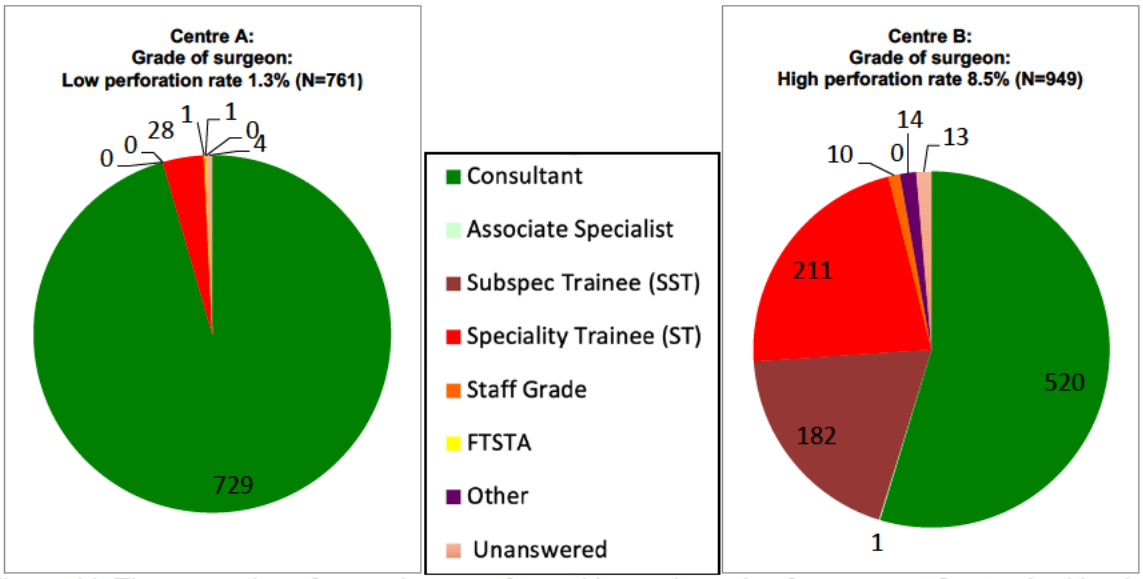


Figure 44: The proportion of procedures performed by each grade of surgeon at Centre A with a low overall perforation rate of 1.3% compared to centre B with a high overall perforation rate of 8.5%

The other low perforation rate centres all show lower percentages of non-consultant operators.

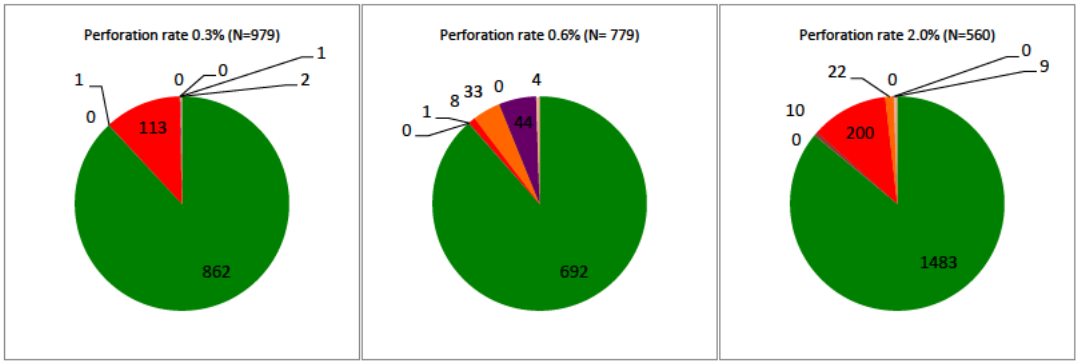


Figure 45: Low perforation rate centres show high consultant operating rates

The other high perforation rate centres all show higher percentages of non-consultant operators.

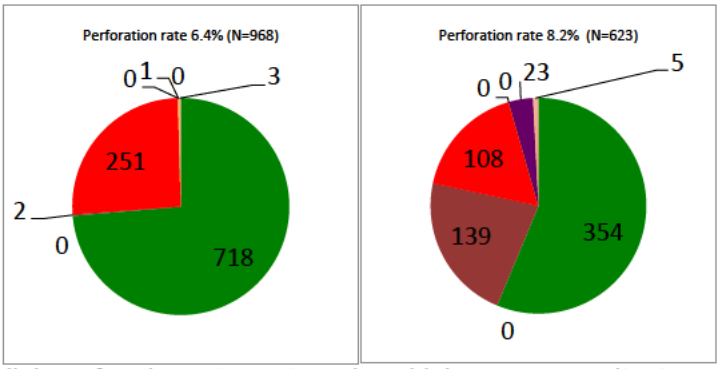


Figure 46: High perforation rate centres show higher non-consultant grade operators

Discussion

These results have shown that there are differences in the patient characteristics, outcomes and complications of patients undergoing RPT and PUB entered onto the BSUG database. RPT were more successful than PUB in terms of PGII and change in SUI symptoms. RPT were also more likely to lead to de novo OAB symptoms. PUB were associated with fewer complications than RPT despite PUB having an older, potentially more complex patient group. Bladder perforation rate was found to be 3.5% for RPT and nil for PUB. There were very few other complications for RPT and nil following PUB without concomitant surgery. Significantly more patients who had RPT compared to PUB required return to theatre, return to hospital and readmission to hospital so these will be included in the further analysis. These are outcomes that are not often recorded as it happens rarely so would not be seen in high frequencies with smaller numbers of participants but is very useful in pre-operative counselling.

These results also show that increased age, BMI, presence of DO on UDS and bladder injury are associated with a reduction in the success rates of RPT. A link between success rates and surgeon grade was not demonstrated but there were more bladder perforations experienced by trainees compared to consultants. These were all simple univariate analysis performed to assess whether there were any significant findings to then move on to the multivariable analysis as detailed in the following chapter. No differences were seen with PGII, SUI or OAB outcomes with age, BMI, grade of operator or UDS for PUB. This may be because the sample sizes were too small or because of the different mechanism of PUB it was thus unaffected by these variables. These findings will be discussed in more detail in the discussion of chapter 3 to avoid duplication of discussion.

This study informs the next chapter with regards to selection of outcome measures. PGII was chosen for the primary outcome as it is validated [110] and commonly used in incontinence outcomes [98, 105-108] and were adequately completed. The change in SUI and OAB questionnaires were selected as secondary outcomes as they have been shown to relate well to symptom improvement, based on Medical Epidemiologic and Social Aspects of Ageing (MESA) scores [128, 129] and were also adequately completed. Although the ICIQ questionnaires [109] potentially offer more objective information with the change in scores pre- and post-operatively, these were not used because of the percentage of missing data.

Despite the change in guidance and the results from VUSIS [32], VALUE [30], and others [189] that show non-inferiority of office evaluation compared to UDS for women with uncomplicated, demonstrable SUI, most clinicians that enter data onto the BSUG database still perform UDS prior to SUI surgery with no change in practice following the publications of these trials.

A wide range of UDS results were seen for both procedures although the most common diagnosis for both was USI as expected. A smaller percentage of PUB patients had pure USI with a correspondingly larger percentage having some element of DO in their urodynamics. It may be that patients were preferentially offered PUB to avoid the risk of developing or worsening OAB post operatively which was seen more with RPT, but this cannot be confirmed as there is no information on the decision making. Alternatively, this may reflect that there were higher rates of complex diagnoses in elderly patients. It was not possible to know what other strategies had been tried, such as medications, before and after operations and this would only be

possible if it were a longitudinal disease-based database rather than a surgical database.

It was likely that the 3-4% patients that had a RPT who did not undergo UDS had uncomplicated SUI with normal voiding and no symptoms of OAB. The patients that had a RPT without having UDS had positive outcomes, which would suggest that with the correct patient selection, UDS are not required, supporting the NICE guidance [12] that these patients do not need UDS. Unfortunately due to the set-up of the database it was not possible to know the history reported by the patient or what other examinations or investigations they have had. As these patients are likely to have very straightforward symptoms, they are in a way a self-selected group that are likely to be successful. The results also show that patients with more complex results from UDS have poorer outcomes and supports the argument that complex symptoms should have UDS to help inform patients of the likelihood of success and potential risk of poorer outcomes from surgery.

Follow up method and length of time after the operation for patient review was variable. The introduction of an electronic automatic follow-up, such as by mobile phone app, would improve this and unify and increase the follow up and reduce bias.

Discussion: Bladder perforation

The rate of bladder damage is lower than the value of 4.5% from the most recent Cochrane review [55]. One explanation for this may be that the clinicians who use the database are a self-selected group who are confident to have their figures audited. It could be that some older papers in the Cochrane review included surgeons still going

through their learning curve. Alternatively it may be that the database data entered is not correct, either by design or accident. A validated database with audit would ensure accurate reporting.

A range of perforation rates were seen at different centres shown on the funnel plot. The centres with lower numbers of procedures have much wider ranges because a few perforations would have a much greater effect. As the total numbers in each centre increase, the appearance of the funnel plot does not tend towards the overall perforation rate, the opposite has been shown, and *all* the centres with the greatest numbers of cases, (more than 700) are outliers. Lying under the lower limit shows an impressive low level of complications. Lying above the curve requires investigation. A higher perforation rate was seen in those centres with high numbers of trainees performing the procedures and a lower perforation rate was seen in those centres with a low number of trainees performing the procedures.

Procedural experience [49, 194] has been shown to have a significant effect on surgical complication rates with clinicians of greater experience having lower complication rates. A higher perforation rate was seen in trainees which explains the higher perforation rate in centres with a large proportion of cases performed by trainees. Trainees are a heterogeneous group and a single trainee who is already competent is likely to have a lower perforation rate than a group of trainees all early in their learning curve [49]. Data were available to establish how many procedures were performed by trainees at each centre, but necessarily specific details of individual trainees were not provided for data protection. As such it was not possible to establish how many trainees were operating at each centre and where they were on their

learning curve or acknowledge that each one of them will have their own learning trajectory. Additionally individual consultants may vary the technique for the trainee moving them back on that curve. It was not possible to know the level of supervision. There has been minimal literature on the success of RPT by grade of the operator as RCTs are generally performed by experienced surgeons. As it is not practical to prevent trainees operating, to avoid the higher perforation rate, the best ethical option is to limit the number of trainees on the learning curve by only permitting trainees with a specific demonstrable interest in urogynaecology to perform RPT and to use simulation training with models [195, 196].

A lower perforation rate was seen with increased BMI. It is possible that the reduced incidence of perforation is due to the optimal amount of perivesical adipose tissue cushioning to protect the bladder, but no evidence for this can be found in the literature. This could be further investigated by looking at MRI scans of high BMI patients and particularly now, with the increased scanning of RPT due to the longer-term complications, the course of the RPT through the pelvis could be identified on MRI.

A funnel plot could be used for benchmarking if appropriate levels are set. Benchmarking allows for self-reflection and analysis of clinical skills and surgical techniques. A funnel plot such as this could potentially be used by individual clinicians to assess performance and give early indicators if they are above the upper limits of the range, however with this variety in perforation rate with grade of surgeon and BMI shown here it would not be advisable without careful risk adjustment. Also this database is not validated so cannot be used for this benchmarking. If a risk adjustment strategy could be implemented, then this information could be used as evidence in

appraisals. If a clinician has a low complication rate with routine cases, they can be justified in operating on more complicated or difficult cases. If a higher complication rate is seen, practice can be supervised or adjusted to work towards lower complication rates. It would be beneficial to identify units where there is a high success and low complication rate and learn from them. Surgical expertise is likely to be important, but preparation, selection and aftercare of patients will also play a part.

Weakness of this analysis

As it is database research, by definition, it does not control case selection and hence, the potential differences in patient selection and surgeon decision making are acknowledged as limitations, as shown in characteristics of patients who undergo the two procedures (and the unassessed importance different clinicians placed on them), and this may have biased the results. A multivariable regression analysis is required to correct for these differences.

There was a high volume of missing outcome data. The baseline characteristics highlight the amount of missing data which was a major source of bias in this work. Age, anaesthetic, and grade of operator had high completion levels with only 1-4% missing data, UDS and PFMT were less well completed with 9.5-18% missing and BMI was the lowest with 36-46% missing. From personal practical experience of completing the database and communication with other clinicians, age of patient is simple to locate as it is on the sticker or an operating list and the anaesthetic and grade of operator is easy as the operation has just been performed at the time of database completion. UDS would be known as the clinical case would have been reviewed just prior to the operation. BMI is often only found in the patient paper notes which may not be with the clinician at the time so this may contribute to poor completion.

The outcome numbers will always be slightly lower than the true result as the database is live, so a delay of up to 12 months will occur after entry on the database while the patient waits for follow up. Missing data is a common limitation in database research. It is likely however that the missing data will be uniform throughout both procedures

as they are from the same database. Patients were removed from the analysis if that data point was missing so there is the acknowledgement that bias could be introduced here for the pilot study and with multiple imputation planned for the secondary analysis.

Further discussion of the strengths and weaknesses of the BSUG database is included in chapter 5 to avoid duplication.

Future research

A grant was applied for, and the assistance of statisticians sought to further study the identified characteristics of age, BMI, UDS, grade of operator, and bladder injury where the missing data will be overcome using multiple imputations.

Conclusions

The data in the BSUG database would suggest that RPTs were more successful than PUB in terms of PGII and cure/improvement of SUI symptoms. However they were also more likely to lead to increased OAB symptoms and other operative and post operative complications compared to PUB. Increased age, BMI, DO in UDS and bladder injury have been shown to led to worse outcomes with RPT in this basic univariable analysis and will be brought forward to the subsequent analysis. The results must be viewed with cognisance of the weaknesses present in all database research in that there may be bias in patient selection and there is incomplete data. Factors to improve this database would be to make it validated, have mandatory fields and to include time regulated follow up collected in isolation from the operating team.

Chapter 3: Multivariable analysis of outcomes of stress urinary incontinence surgery

Background

As the situation developed with mesh tapes being removed from the UK, the analysis needed to be expanded to include AFS and colposuspension as they were increasingly performed in the absence of mesh tapes. Many of the literature regarding these procedures is older as they have been less commonly performed in recent years. The pilot analysis (Chapter 2) demonstrated differences in outcomes for RPT with BMI, UDS and grade of operator yet this only considered each variable in isolation therefore a multivariable analysis was required to ensure all variables were included.

The vision was, that this information could be used in a prediction model to allow patients to assess their *personal* risks and likely outcomes for each procedure to be able to make a more informed decision based on their clinical characteristics and acceptable risk profile. For this to be robust and valuable, the data utilised for the development of the model is required to meet certain standards as it would be used to influence clinical decision making. The data needs to be representative, reproducible and reliable.

Objectives

The primary objective of this study was to determine and compare the patient reported outcomes and complications following RPT, PUB, AFS and colposuspension for patients entered on the BSUG database using a multivariable analysis. The secondary objective was to ascertain whether any patient or surgical characteristics entered onto

the database affected these outcomes for each procedure again using a multivariable analysis.

Methods

Acquiring the data

This was a retrospective cohort study, performed using a dataset sourced from the BSUG database for female patients undergoing surgery for SUI from the commencement of the database in 2008 to March 2019. Data were acquired similarly to the pilot study (appendix 1) with a two-stage application process to BSUG. Anonymisation, consent and data protection regulations were identical to the previous analysis (chapter 2). Data were extracted from the database by the IT company and was received as an Excel spreadsheet containing all data points recorded on the BSUG database for the requested patients.

Study population

Patients from the BSUG database, were included if they underwent RPT, PUB, AFS or colposuspension (open, laparoscopic) under NHS or private care in the UK. The primary population was defined as patients who were having their first SUI surgery without other major concomitant surgery and was the cleanest population as there was no interference from concomitant surgery or previous SUI procedures. The secondary population was all patients from eligible centres to allow a comparison between first and repeat surgery.

Classification and grouping of procedures

Whilst a vast number of commercial products have been used for RPT and PUB, a decision was made only to include the main products in the groups and exclude those

products with small numbers. Patients were included if they underwent RPT using Advantage, Advantage Fit or TVT and for bulking agents Bulkamid, Collagen, Contigen, Macroplastique and Tegress were used. All fascial sling techniques were included as the Aldridge style and the sling on a string (SOAS) have been found to be equally as effective [197]. Open and laparoscopic colposuspension were grouped together as similar success rates with both techniques are seen [198, 199].

Centre inclusion

Only patients from centres that reported ≥10 incontinence procedures in any given year were included to reflect centres that reported regularly rather than on an ad hoc basis. See appendix 5 for further rationale.

Sample size calculations

There was no prospective sample size calculation as all available data was used. However, to identify a difference of 5% (90% vs 85%) in the primary outcome of PGII between groups, would require 918 participants per group (1836 total number of participants) to achieve 90% power at a significance level of 5%.

Outcome measures

The primary outcome was the validated PGII [110] as previously described. This was categorised into two groups of “better” (very much better, much better) and “not better” (little better, no change, little worse, much worse and very much worse) for analysis.

Secondary outcomes included change in SUI symptoms and change in OAB symptoms as described above. If a patient reported their SUI was “cured” or

“improved”, this was counted as success, compared to “no change” or “worse”. OAB was treated differently as there were two groups of patients: those with pre-operative OAB symptoms and those without. If patients had pre-operative OAB symptoms, their options for reporting would be cured, improved, no change or worse. If they did not have pre-operative OAB symptoms their options would be de novo OAB or that OAB had never been present. Other secondary outcomes were bladder injury, return to theatre for procedure-related event within 72 hours, return to hospital within 30 days for procedure related event and readmitted to hospital within 30 days for procedure related event.

Statistical analysis

Baseline measures were summarised as frequency and percentages for categorical variables and mean and standard deviation or median and interquartile ranges for continuous measures where appropriate.

Multivariable logistic regression

Multivariable logistic regression was used. The model for the primary analysis included all treatments in the primary population to allow comparisons across all 4 procedures, with RPT being designated the reference treatment. The secondary analysis included each treatment in separate models to identify characteristics that altered the outcome of that procedure. Odds Ratios (OR), 95% confidence intervals and p-values were reported for all analyses. Covariates included age, BMI, PFMT, pre-operative UDS, grade of operator, bladder injury and whether the surgery was the first SUI surgery or a repeat. These were chosen as they had been identified from the work performed in

Chapter 2, in previous analyses [186, 187, 200] or the clinical team deemed them important.

Multiple imputation using chained equations was used for each of the treatment datasets separately, between 63 and 81 imputations were used based on the fraction of missing data, with imputations combined using Rubin's rules [143, 201]. Analysis of the data was performed using Stata v16 (StataCorp College Station TX), by University of Birmingham statisticians using funding from a grant (appendix 1).

Optimising covariates

Age <18 and >100 were excluded and it was managed as a continuous variable for analysis. It was felt that women under 18 would rarely be having a procedure for SUI and therefore considered a special case to be managed on an individual case by case basis. Age over 100 was considered to be an error. For the patient characteristics description, age was categorised into 18-50, 50-80 and 80-100 years to separate pre-menopausal, post-menopausal and elderly women.

Similarly, BMI <15 and >65 were excluded as anything out with these would likely be an error and if it were not then they would be managed on a case by case basis. For patient characteristics, BMI was categorised into <18.5 underweight, 18.5 to <25 healthy, 25.0 to <30 overweight, 30 to < 35 Class 1 obesity, 35 to < 40 class 2 obesity and >40 class 3 severe obesity. BMI is calculated by the database when the clinician enters the weight and the height of the patient. For the data entries of both weight and height there were values that were expected to be found (within 'normal limits'), data that was entered for wrong units (cm instead of m for height) and values that were

obviously incorrect. A decision was made to amend the data that was clearly in the incorrect units to limit missing data.

Information regarding pelvic floor muscle training is entered on to the database and PFMT was said to have occurred if they were offered and accepted.

Pre-operative urodynamic diagnoses were rationalised into 3 options as listed below with further information regarding this in appendix 6.

1. USI and USI + voiding dysfunction
2. DOA, Mixed and Mixed and voiding dysfunction
3. Not completed, Normal, Voiding dysfunction

Grade of operator was defined as consultant vs non-consultant grades which included subspecialty trainee, specialty trainee, staff grade, associate specialist and other. A surgery was defined as ‘first’ if it was the first SUI surgery and ‘repeat’ if any previous SUI surgery had been performed.

The odds ratios for age relate to the change per decade, for BMI relate to change per unit of BMI, for PFMT compare undergoing and not undergoing PFMT, UDS compares “DOA, Mixed and Mixed and voiding dysfunction” and ‘Not completed, Normal, Voiding dysfunction’ to the reference of ‘USI and USI + voiding dysfunction’, grade of operator compares consultant to non-consultant grade, bladder injury compares presence or absence of injury and first vs repeat surgery is self-explanatory.

A statistical report and statistical errors are recorded in appendix 11 and 12. Full statistical tables are recorded in appendixes 7 – 10.

Results

There were 31,901 procedures available for analysis. RPT were the most common procedure performed (n=24,923; 78.1%), then PUB (n=4740; 14.8%), colposuspension (n=1700; 5.3%) and AFS (n=538; 1.7%). Figure 47 shows how the recorded treatments changed over time. Numbers of mesh procedures fell in 2017, and PUB became rapidly more popular with a slower increase in colposuspension and AFS. In 2013 HQIPP undertook a national audit [43] which explains the increase in the procedures recorded (rather than a change in practice). The reduction in cases entered after 2016, reflects an overall reduction in SUI surgery performed, rather than clinicians leaving the database, as demonstrated by the increased percentage of cases from the HES data entered onto the database [22, 126].

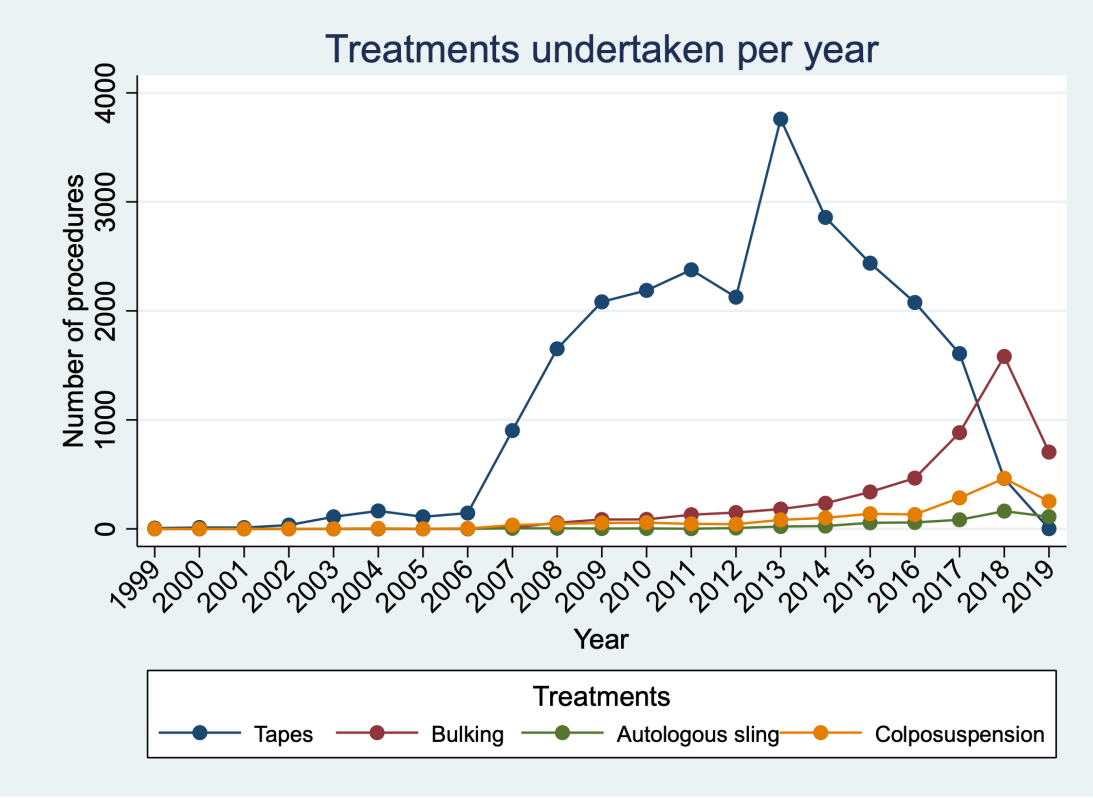


Figure 47: Stress urinary incontinence procedures per year as recorded on the BSUG database (Data were retrieved in March 2019 so for that year there was only a quarter of the projected numbers of procedures)

Patient characteristics

For the primary population, the mean ages of patients receiving RPT, AFS and colposuspension were similar and whereas a higher mean age was seen in PUB (table 19). A greater proportion of patients receiving PUB were over 80 years (166/2237 (7.4%)) compared to RPT, AFS and colposuspension (230/15478 (1.5%), 1/171 (0.6%) & 3/697 (0.4%)).

The mean BMI of all procedures were similar between surgeries (Table *19*). Between 90-92% of patients were documented to have had PFMT. The most common urodynamic diagnosis was urodynamic stress incontinence (USI) for all procedures (table 19). Most procedures were performed by consultants. RPT had the lowest proportion performed by consultants (78.3%) and the highest by specialty trainees (13.3%). AFS and colposuspension had slightly higher percentages performed by consultants (82.4% and 84.1%) with fewer specialty trainees (2.9% and 4.3%) with higher proportions of subspecialty trainees (14.1% and 10.5%). PUB had the highest proportion performed by consultants (88.2%) with specialty trainees and subspecialty trainees performing lower percentages (5.4% and 4.8%).

For the secondary population, which includes both first and repeat surgeries to allow comparison of first and repeat surgeries; age, BMI, PFMT, UDS diagnosis and grade of operator were similar to the primary population and the patient characteristics can be found in appendix 9 table 1. For the secondary population, 94.2% (n=22742/24153) of RPT were the first SUI surgery compared to primary PUB (73.5% n = 3220/4380), primary AFS (57.1% n=285/499) and primary colposuspension (78.8% n = 1248/1584).

Treatment	RPT	PUB	AFS	Colposuspension
N=19106	n=15885	n=2316	n=177	n=728
Age (years) mean (SD)	51.66 (11.48)	55.31 (15.61)	48.55 (11.04)	49.32 (10.66)
m ss ng,	407	79	6	31
Age categories, n(%)				
Age ess than 50	7621 (49.2%)	909 (40.6%)	98 (57.3%)	367 (52.7%)
Age between 50-79	7627 (49.3%)	1162 (51.9%)	72 (42.1%)	327 (46.9%)
Age 80 and over	230 (1.5%)	166 (7.4%)	1 (0.6%)	3 (0.4%)
M ss ng	407	79	6	31
BMI, mean (SD)	28.38 (4.94)	29.06 (5.40)	28.29 (4.55)	28.53 (4.77)
m ss ng, n	8340	1596	113	401
BMI categories				
Underwe ght	19	2	0	0
Hea thy we ght	2077	176	15	88
Overwe ght - ower	2884	262	30	117
Overwe ght – upper	1730	173	13	86
Obese	835	107	6	36
M ss ng	8340	1596	113	401
Pelvic floor exercises offered, n(%)				
Yes and accepted	12888	1863	148	600
Yes but dec ned	453	59	4	30
No	835	127	8	36
M ss ng	1709	267	17	62
Pelvic floor exercises, n(%)				
Yes	12888 (90.9%)	1863 (90.9%)	148 (92.5%)	600 (90.1%)
No	1288 (9.1%)	186 (9.1%)	12 (7.5%)	66 (9.9)
M ss ng	1709	267	17	62
Pre-op urodynamic diagnosis, n				
USI	11274	1548	127	564
USI + vo d ng dysfunct on	352	75	2	15
Norma	385	64	2	7
M xed	2281	377	27	71
M xed + vo d dysfunct on	78	11	0	5
DOA	62	15	0	1
Vo d ng dysfunct on	4	7	0	1
Not comp eted	488	53	9	7
M ss ng	961	166	10	57

Treatment	RPT	PUB	AFS	Colposuspension
Pre-op urodynamic diagnosis, n(%)				
USI, USI + Vo d Dysfunct	11626 (77.9%)	1623 (75.5%)	129 (77.2%)	579 (86.3%)
DOA, m xed, m x +vo d dys	2421 (16.2%)	403 (18.7%)	27 (16.2%)	77 (11.5%)
Norma , vo d dys, not done	877 (5.9%)	124 (5.8%)	11 (6.6%)	15 (2.2%)
M ss ng	961	166	10	57
Grade of operator, n(%)				
Consu tant	12299 (78.3%)	2003 (88.2%)	140 (82.4%)	608 (84.1%)
Assoc ate Spec a st	114 (0.7%)	1 (0.0%)	0 (0.0%)	3 (0.4%)
Subspec Tra nee (SST)	867 (5.5%)	108 (4.8%)	24 (14.1%)	76 (10.5%)
Spec a ty Tra nee (ST)	2086 (13.3%)	123 (5.4%)	5 (2.9%)	31 (4.3%)
Staff grade	170 (1.1%)	31 (1.4%)	1 (0.6%)	1 (0.1%)
FTSTA	7 (0.0%)	0 (0.0%)	0 (0.0%)	1 (0.1%)
Other	160 (1.0%)	4 (0.2%)	0 (0.0%)	3 (0.4%)
M ss ng	182	46	7	5
Grade of operator, n(%)				
Consu tant	12299 (78.3)	2003 (88.2%)	140 (82.4%)	608 (84.1%)
Non consu tant	3404 (21.7%)	267 (11.8%)	30 (17.6%)	115 (15.9%)
M ss ng	182	46	7	5

Table 19: Patient and surgical characteristics of RPT, PUB, AFS and colposuspension for the primary population

Primary analysis: comparison across treatments: Primary population: Primary outcome

For patients in the primary population with a reported outcome, 91% (9175/10084) recorded a 'better' outcome for PGII following RPT, 89.1% (57/64) for AFS and 87.4% (353/404) for colposuspension with a lower proportion for PUB of 56.6% (721/1273) (Table 20). Multivariable analysis showed an 87% reduction in the odds of a positive outcome for PGII following PUB compared to RPT which is statistically significant (OR 0.13; 95% CI: 0.09,0.17; p<0.001) (Table 22).

Primary analysis: comparison across treatments: Primary population: Secondary outcomes

For patients in the primary population, 96.7% (9131/9443) patients reported a cure/improvement of SUI after RPT, 96.7% (59/61) after AFS and 96.7% (376/389) after colposuspension with a lower percentage for PUB of 74.1% (874/1179) (Table 20) resulting in a statistically significant reduction in odds of a positive outcome compared to RPT (OR 0.10; 95% CI: 0.06,0.14; p<0.001) (Table 22). For those patients with pre-operative OAB symptoms, RPT showed the highest percentage of cure/improvement of OAB of 62.4% (3432/5499) compared to 38.6% (260/673) for PUB, 36.4% (12/33) with AFS and 45.9% (102/222) with colposuspension with no statistically significant findings (Table 20).

For those patients without pre-operative OAB, AFS and colposuspension showed the highest percentage of patients reporting new OAB of 16% (4/25) and 14.6% (22/151)

respectively (Table 20) compared to 10% (378/3784) for RPT and a lower odds for PUB (2.4% (10/414) (OR 0.20; 95% CI: 0.05,0.84; p=.028) (Table 22).

The percentage of patients who experienced a bladder injury was similar for RPT (3.6% (569/15692)), AFS (3.4% (6/175)) and colposuspension (3.3% (24/722)) with a significantly lower odds for PUB (0.1% (2/2294)) (OR 0.03; 95% CI: 0.00,0.19; p<0.001) compared to RPT (table 21 & 22).

Return to theatre with 72 hours percentage was similar for RPT (0.5% (59/11513)) and colposuspension (0.4% (2/463)) with no returns to theatre seen with AFS and PUB (table 21).

Return to hospital within 30 days was recorded for 6.8% (231/3377) of RPT patients compared to significantly lower odds with PUB (1.9% (22/1159)) (OR 0.32; 95% CI: 0.19,0.53; p<0.001) and higher odds for patients following AFS (18.5% (12/65)) (OR 2.42; 95% CI: 1.07,5,45; p=0.033) and 7.1% (27/380) for colposuspension (table 21 & 22).

Readmission to hospital within 30 days was recorded for 3.8% (430/10867) of RPT patients compared to 0.7% (10/1402) for PUB (OR 0.22; 95% CI: 0.10,0.47; p<0.001), and higher for AFS with 15.1% (11/73) readmitted (OR 5.81; 95% CI: 2.64,12.75; p<0.001) and colposuspension with 5.5% (25/453) readmitted (table 21 & 22).

Treatment	RPT n=15885		PUB n=2316		AFS n=177		Colposuspension n=728		Total
Population: Non concomitant first surgery									
PGII, n(%)									
Better	9175	91.0%	721	56.6%	57	89.1%	353	87.4%	
Not better	909	9.0%	552	43.4%	7	10.9%	51	12.6%	
Total	10084		1273		64		404		11,825
Missing PGII data	*5801*		*1043*		*113*		*324*		
SUI symptoms, n(%)									
Cured or Improved	9131	96.7%	874	74.1%	59	96.7%	376	96.7%	
No change or Worse	312	3.3%	305	25.9%	2	3.3%	13	3.3%	
Total	9443		1179		61		389		11,072
Missing SUI data	*6442*		*1137*		*116*		*339*		
OAB									
OAB (Patients with pre-operative symptoms), n(%)									
Cured or Improved	3432	62.4%	260	38.6%	12	36.4%	102	45.9%	
No change or Worse	2067	37.6%	413	61.4%	21	63.6%	120	54.1%	
Total	5499		673		33		222		6,427
OAB (Patients without pre-operative symptoms), n(%)									
New symptoms	378	10.0%	10	2.4%	4	16.0%	22	14.6%	
Never present	3406	90.0%	404	97.6%	21	84.0%	129	85.4%	
Total	3784		414		25		151		4,374
Missing OAB data	*6602*		*1229*		*119*		*355*		

Table 20: Patient reported outcomes following RPT, PUB, AFS and colposuspension: Primary population

Bladder injury									
Yes	569	3.6%	2	0.1%	6	3.4%	24	3.3%	
No	15123	96.4%	2292	99.9%	169	96.6%	698	96.7%	
Total	15692		2294		175		722		18,883
Missing	*193*		*22*		*2*		*6*		
Return to theatre for procedure-related event within 72 hours									
Yes	59	0.5%	0	0.0%	0	0.0%	2	0.4%	
No	11454	99.5%	1418	100%	72	100%	461	99.6%	
Total	11513		1418		72		463		13466
Missing	*4372*		*898*		*105*		*265*		
Return to hospital within 30 days for procedure related event									
Yes	231	6.8%	22	1.9%	12	18.5%	27	7.1%	
No	3146	93.2%	1137	98.1%	53	81.5%	353	92.9%	
Total	3377		1159		65		380		4981
Missing	*12508*		*1157*		*112*		*348*		
Readmitted to hospital within 30 days for procedure related event									
Yes	430	3.8%	10	0.7%	11	15.1%	25	5.5%	
No	10867	96.2%	1392	99.3%	62	84.9%	428	94.5%	
Total	11297		1402		73		453		13225
Missing	*4588*		*914*		*104*		*275*		

Table 21: Complications reported following RPT, PUB, AFS and colposuspension: Primary population

Outcome		Result compared to RPT Univariable	Result compared to RPT Multivariable
PGII	PUB	OR 0.10; 95% CI: 0.09,0.12; p<0.001*	OR 0.13; 95% CI: 0.09,0.17; p<0.001*
	AFS	OR 0.69; 95% CI: 0.30,1.55; p=0.367	OR 1.12; 95% CI: 0.25,4.93; p=0.882
	Colpos'n	OR 0.67; 95% CI: 0.48,0.92; p=0.014*	OR 0.96; 95% CI: 0.56,1.65; p=0.874
SUI symptoms	PUB	OR 0.08; 95% CI: 0.06,0.09; p<0.001*	OR 0.10; 95% CI: 0.06,0.14; p<0.001*
	AFS	OR 0.89; 95% CI: 0.21,3.76; p=0.874	OR 0.26; 95% CI: 0.06,1.17; p=0.079
	Colpos'n	OR 0.95; 95% CI: 0.53,1.71; p=0.859	OR 1.04; 95% CI: 0.40,2.72; p=0.933
OAB symptoms (pre-op OAB)	PUB	OR 0.59; 95% CI: 0.48,0.73; p<0.001*	OR 1.24; 95% CI: 0.86,1.80; p=0.254
	AFS	OR 0.46; 95% CI: 0.21,1.00; p=0.051	OR 0.61; 95% CI: 0.12,3.06; p=0.550
	Colpos'n	OR 0.94; 95% CI: 0.68,1.29; p=0.681	OR 0.99; 95% CI: 0.60,1.65; p=0.970
OAB symptoms (no pre-op OAB)	PUB	OR 0.59; 95% CI: 0.48,0.73; p<0.001*	OR 0.20; 95% CI: 0.05,0.84; p=0.028*
	AFS	OR 0.46; 95% CI: 0.21,1.00; p=0.051	OR 2.53; 95% CI: 0.51,12.68; p=0.259
	Colpos'n	OR 0.94; 95% CI: 0.68,1.29; p=0.681	OR 1.11; 95% CI: 0.46,2.66; p=0.822
Bladder injury	PUB	OR 0.02; 95% CI: 0.01,0.10; p<0.001*	OR 0.03; 95% CI: 0.00,0.19; p<0.001*
	AFS	OR 0.71; 95% CI: 0.29,1.73; p=0.449	OR 1.45; 95% CI: 0.50,4.25; p=0.496
	Colpos'n	OR 0.80; 95% CI: 0.51,1.27; p=0.346	OR 0.92; 95% CI: 0.50,1.68; p=0.776
Return to theatre		unable to complete as no returns to theatre for PUB or AFS	
Return to hospital (RTH) within 30 days	PUB	OR 0.25; 95% CI: 0.16,0.40; p<0.001*	OR 0.32; 95% CI: 0.19,0.53; p<0.001*
	AFS	OR 2.52; 95% CI: 1.24,5.10; p=0.010*	OR 2.42; 95% CI: 1.07,5.45; p=0.033*
	Colpos'n	OR 1.01; 95% CI: 0.64,1.59; p=0.964	OR 1.05; 95% CI: 0.62,1.78; p=0.848
Readmitted to hospital (RdTH)	PUB	OR 0.20; 95% CI: 0.11,0.39; p<0.001*	OR 0.22; 95% CI: 0.10,0.47; p<0.001*
	AFS	OR 4.84; 95% CI: 2.43,9.65; p<0.001*	OR 5.81; 95% CI: 2.64,12.75; p<0.001*
	Colpos'n	OR 1.44; 95% CI: 0.93,2.25; p=0.104	OR 1.56; 95% CI: 0.93,2.61; p=0.092

Table 22: Primary analysis: Comparison across treatment: Primary population: Univariable and multivariable comparison of outcomes: (Full data in appendix 7 table 2-8)

Secondary analysis: Comparison within treatments: The effect of patient and operative characteristics on outcomes: Primary population: Primary outcome

Patient and operative characteristics do alter the patient reported outcomes and complications in the BSUG database as described below. Only significant results are presented here with full data in appendix 8.

For RPT, the odds of a positive outcome of PGII reduced with: increased age (OR 0.83; 95% CI: 0.77,0.90; p<0.001), increased BMI (OR 0.95; 95% CI: 0.93,0.97; p<0.001), pre-operative urodynamic diagnosis that included overactivity (OR 0.51; 95% CI: 0.41,0.64; p<0.001) and intra-operative bladder injury (OR 0.57; 95% CI: 0.37,0.89; P=0.012) (Table 24). Written in a different way: for every 10 years older a woman was there was a 17% decrease in the odds of success of PGII. If the patient had a bladder injury there was a 43% reduction in odds of success of PGII.

Secondary analysis: Comparison within treatments: The effect of patient and operative characteristics: Primary population: Secondary outcomes

For RPT, the same characteristics were also found to reduce the odds of a cure/improvement of SUI: increased age (OR 0.81; 95% CI: 0.72,0.91; p<0.001), increased BMI (OR 0.96; 95% CI: 0.93,0.99; p=0.009), pre-operative urodynamic diagnosis that included overactivity (OR 0.65; 95% CI: 0.45,0.93; p=0.017) and bladder injury (OR 0.38; 95% CI: 0.21,0.71; p=0.002). For RPT, greater odds of developing new post-operative OAB were seen with increased age (OR 1.20; 95% CI: 1.06, 1.36; p=0.003) and non-consultant grade operator (OR 1.5; 95% CI: 1.07,2.09; p=0.018). For RPT, an increased BMI was associated with reduced odds of bladder

injury (OR 0.93; 95% CI: 0.90,0.96; p<0.001) and a non-consultant grade operator was associated with increased odds of bladder injury (OR 3.88; 95% CI: 2.99, 5.05; p <0.001). Increased odds of return to theatre following RPT was seen with non-consultant grade operator (OR 3.81; 95% CI: 1.96,7.41; p<0.001) and bladder injury (OR 4.23; 95% CI: 1.81,9.90; p=0.001). Bladder injury was the sole factor associated with increased odds of readmission to hospital for RPT (OR 2.10; 95% CI: 1.23,3.58; p=0.006) (table 23).

Characteristics studied did not significantly alter the outcomes for PUB.

For AFS, the characteristics studied did not significantly alter the success rates however there was a significantly increased odds of readmission to hospital with increased age (OR 2.03; 95% CI: 1.10,3.77; p=0.024) (table 23).

For colposuspension, increased age led to reduced odds of a cure/improvement of SUI (OR 0.47; 95% CI: 0.25,0.87; p0.017), increased odds of bladder injury (OR 1.67; 95% CI: 1.03,2.71; P=0.036), return to hospital (OR 2.03; 95% CI: 1.31,3.16; p=0.002) and readmission to hospital (OR 1.82; 95% CI: 1.12,2.95; p=0.016) (table 23).

Secondary analysis: Comparison within treatments: The effect of patient and operative characteristics: Secondary population: Secondary outcomes

The secondary population of ‘all patients’ was used for this analysis as it contained first and repeat surgeries.

Repeat procedures led to reduced odds of success for PGII and cure/improvement of SUI symptoms for RPT (OR 0.68; 95% CI: 0.51,0.92; p=0.012, OR 0.55; 95% CI: 0.36,0.83; p=0.004), PUB (OR 0.66; 95% CI: 0.45,0.96; p=0.031, OR 0.58; 95% CI: 0.37,0.91; p=0.018) and colposuspension (OR 0.43; 95% CI: 0.22,0.86; p=0.016, OR 0.23; 95% CI: 0.08,0.66; p=0.006). An increased odds of bladder injury (OR 1.67; 95% CI: 1.10,2.53; p=0.016) was seen with repeat RPT compared to first surgery (table 25).

Retropubic tapes		
Significantly *reduced* odds of positive outcome **PGII** with (appendix 8 table 1)	increased age	OR 0.83; 95% CI: 0.77,0.90; p<0.001
	increased BMI	OR 0.95; 95% CI: 0.93,0.97; p<0.001
	UDS includes DO vs USI, USI + voiding dysfunction	OR 0.51; 95% CI: 0.41,0.64; p<0.001
	bladder injury	OR 0.57; 95% CI: 0.37,0.89; P=0.012
Significantly *reduced* odds **cure/improvement SUI** with (appendix 8 table 2)	increased age	OR 0.81; 95% CI: 0.72,0.91; p<0.001
	increased BMI	OR 0.96; 95% CI: 0.93,0.99; p=0.009
	UDS includes DO vs USI, USI + voiding dysfunction	OR 0.65; 95% CI: 0.45,0.93; p=0.017
	bladder injury	OR 0.38; 95% CI: 0.21,0.71; p=0.002
Significantly *increased* odds **new OAB** in patients with no pre-operative OAB with (appendix 8 table 4)	increased age	OR 1.20; 95% CI: 1.06, 1.36; p=0.003
	non-consultant vs consultant	OR 1.5; 95% CI: 1.07,2.09; p=0.018
Significantly *reduced* odds **bladder injury** with (appendix 7 table 5)	increased BMI	OR 0.93; 95% CI: 0.90,0.96; p<0.001
Significantly *increased* odds **bladder injury** with (appendix 8 table 5)	non-consultant vs consultant	OR 3.88; 95% CI: 2.99, 5.05; p <0.001
Significantly *increased* odds **return to theatre** with (appendix 8 table 6)	non-consultant vs consultant	OR 3.81; 95% CI: 1.96,7.41; p<0.001
	bladder injury	OR 4.23; 95% CI: 1.81,9.90; p=0.001
Significantly *increased* odds **readmission to hospital** with (appendix 8 table 8)	bladder injury	OR 2.10; 95% CI: 1.23,3.58; p=0.006
Autologous Fascial Sling		
Significantly *increased* odds of **readmission to hospital** with (appendix 8 table 24)	increased age	OR 2.03; 95% CI: 1.10,3.77; p=0.024
Colposuspension		
Significantly *decreased* odds **cure/improvement SUI** with (appendix 8 table 26)	increased age	OR 0.47; 95% CI: 0.25,0.87; p0.017
Significantly *increased* odds of **bladder injury** with (appendix 8 table 29)	increased age	OR 1.67; 95% CI: 1.03,2.71; P=0.036
Significantly *increased* odds of **return to hospital** with (appendix 8 table 31)	increased age	OR 2.03; 95% CI: 1.31,3.16; p=0.002
Significantly *increased* odds of **readmission to hospital** with (appendix 8 table 32)	increased age	OR 1.82; 95% CI: 1.12,2.95; p=0.016

Table 23: Characteristics in the primary population that lead to a change in the odds of success for RPT, AFS and colposuspension on multivariable analysis. This only includes the significant results with the full results recorded in appendix 8

RPT	Populations: Non-concomitant First surgery		
Primary outcome: PGII			
No change vs Better			
(No change: A tt e better, No change, a tt e worse, much worse, very much worse			
Better: Very much better, much better)			
n=5914			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.83	(0.77,0.90)	<0.001
BMI	0.95	(0.93,0.97)	<0.001
PFMT	1.11	(0.84,1.47)	0.472
Preoperative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.51	(0.41,0.64)	<0.001
Norma , vo d ng dysfunct on, not comp eted	0.92	(0.60,1.43)	0.718
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.85	(0.68,1.06)	0.146
Bladder injury	0.57	(0.37,0.89)	0.012

Table 24: Patient characteristics associated with change in outcome for the secondary analysis, primary outcome (PGII), primary population (all other results are shown in appendix 8&10)

Retropubic tapes		
Significantly *reduced* odds of positive outcome **PGII** with (appendix 10 table 1)	Repeat procedure	OR 0.68; 95% CI: 0.51,0.92; p=0.012
Significantly *reduced* odds **cure/improvement SUI** with (appendix 10 table 2)	Repeat procedure	OR 0.55; 95% CI: 0.36,0.83; p=0.004
Significantly *increased* odds **bladder injury** with (Appendix 10 table 5)	Repeat procedure	OR 1.67; 95% CI: 1.10,2.53; p=0.016
Periurethral bulking agent		
Significantly *reduced* odds of positive outcome **PGII** with (appendix 10 table 9)	Repeat procedure	OR 0.66; 95% CI: 0.45,0.96; p=0.031
Significantly *reduced* odds **cure/improvement SUI** with (appendix 10 table 10)	Repeat procedure	OR 0.58; 95% CI: 0.37,0.91; p=0.018
Colposuspension		
Significantly *reduced* odds of positive outcome **PGII** with (appendix 10 table 25)	Repeat procedure	OR 0.43; 95% CI: 0.22,0.86; p=0.016
Significantly *reduced* odds **cure/improvement SUI** with (appendix 10 table 26)	Repeat procedure	OR 0.23; 95% CI: 0.08,0.66; p=0.006

Table 25: Outcomes where repeat procedures lead to a change in the odds of success for RPT, PUB and colposuspension on multivariable analysis (secondary population). This only includes the significant results with the full results recorded in appendix 10

Discussion

This analysis from the BSUG database represents more cases than other retrospective reviews and has been performed using data at a national level.

The most common procedure for SUI, reported on the BSUG database, was RPT, followed by PUB, then colposuspension, with AFS less commonly reported. A dramatic shift in popularity of procedures was seen through the last twenty years. Surgery for SUI had been dominated by mesh tapes and this can be explained by several reasons. There was increased uptake of SUI procedures when the mesh tapes were introduced due to relative ease of procedure, reduced surgical time, and reduced morbidity compared to previous older, more invasive operations [55, 56]. The Department of Health Hospital Episode Statistics (HES) showed that in 2001, midurethral mesh tape overtook colposuspension as the most frequently performed procedure for SUI in the UK [3] and their success led to them replacing colposuspension as the clinician perceived 'gold standard procedure' for SUI [57]. The majority of females undergoing surgery for SUI in the 21st century received a midurethral mesh sling without consideration of other options.

The popularity of mesh tapes declined due to the increased awareness of long term complications with mesh procedures through the early to mid 2010s [112, 113] which led to patients and clinicians being more cautious of mesh procedures. There was a decline in disease presentation rate and this, coupled with the impact of NICE guidance [12] and greater use of PFMT, led to a decline in procedures being performed. This culminated in the mesh 'pause' mandated by the UK government following the Cumberlege report [114]. The increase in popularity of PUB, over AFS

and colposuspension from 2018, is most likely due to their relative ease of procedure in comparison to the more complex techniques of colposuspension and AFS. Consultants trained after the rise in popularity of RPT may not have learnt AFS with the original Aldridge technique [14] so would either need to learn that, or more likely adopt the SOAS [51] which is a newer technique where the retropubic mesh and fascial sling techniques have been combined, both techniques require additional training. Additionally, colposuspension was not widely performed, due to the ease of mesh tapes, so consultants would require retraining particularly with the laparoscopic technique. The PUB are more accessible without intense training so increased in popularity. Regional MDT meetings can facilitate effective channels of communication between clinicians to allow patients to travel for alternative procedures if they are not offered by their base hospital.

Baseline characteristics

Patients undergoing PUB were older than women undergoing other procedures with no difference seen in BMI between the groups. Most patients had received PFMT. Most patients had USI for UDS. Consultants performed the majority of the procedures, and this was more pronounced in PUB with the lowest percentage for RPT.

The finding that patients undergoing PUB were older may be due to the fact that historically this has been seen as more of a salvage procedure [50] and so reserved for patients wishing to avoid increased surgical risks of the larger operations and the risk of urinary retention and subsequent catheterisation that can be a sequelae of the more obstructive procedures. It is very likely that the mean age for PUB will decrease to be similar to the others as they increase in popularity as a primary procedure following the mesh pause. There were very small numbers of RPT, colposuspension and AFS performed on over 80s and this may reflect a reluctance to offer major surgery to the elderly population in view of anaesthetic risk and post op recovery.

Most procedures entered onto the database were performed by consultants. The higher proportion of consultants, with lower numbers of trainees, performing the PUB is likely to be because the consultants were still on their learning curve, so need to develop their skills prior to teaching junior staff. AFS and colposuspension, at that time, tended to be performed only at larger tertiary units which was reflected in the increased proportion of subspecialty trainees performing these however this is now expected to change with the need for retraining following the mesh pause. The lower proportion of consultants performing RPT was likely because these were the established, more common procedure, so consultants were happy to train juniors, and this was reflected in the higher proportions of specialty trainees performing these.

Primary analysis: comparison across treatments

High levels of success were seen following RPT, colposuspension and AFS for PGII and cure/improvement of SUI with lower levels for PUB. In patients without pre-operative OAB, PUB were less likely to result in de novo OAB.

Absolute success rates for RPT, colposuspension and AFS were found to be similar to published literature [188, 199, 202-204] however there are broad ranges and outcome measures differ which limits comparisons. The 2017 Cochrane review of RCTs or quasi-RCTs found that subjective cure rates for RPT were between 71% and 97% up to 1 year, 77% to 98% from 1-5 years and in the longer term from 51-88% (>5 years) [188]. The results from the BSUG database are within the short-term (up to one year) range for RPT which is reassuring. As this result has been shown in real life practice this suggests the procedure is robust in a more heterogenous setting compared to RCTs. Most literature demonstrated no difference between RPT and AFS [205-209] which was also found in this study. Some papers report colposuspension to be equal to TVT [209, 210] but others showing reduced efficacy [21, 199, 208]. In this study, the univariable analysis showed significantly lower odds of 'better' PGII with colposuspension compared to RPT however this was not seen in the multivariable analysis. This may explain why some papers found RPT and colposuspension to be different if it was a univariable analysis compared to those who performed multivariable. Trials tend to be moderate to very low quality with high or unclear risk of bias particularly in older trials which tended to be AFS and colposuspension as they were less commonly performed in more recent years [21].

The lower success rates seen in PUB is what was expected and has been seen in the recent trial of primary incontinence surgery comparing Bulkamid and TVT [13, 211], a 2017 systematic review [212] and analysis of the DugaBase [94, 171]. A prospective, RCT [13, 211] comparing tension free vaginal tape (TVT) to Bulkamid found that, on analysis at one year, mean satisfaction Visual Analogue Score (VAS) over 80 was reported in 95% of TVT and 59.8% of Bulkamid. There were more favourable objective outcomes for TVT with respect to negative cough test (95% vs. 66%) and combined negative cough and pad test (91% vs. 54%) [213]. It was difficult to compare the results of this BSUG study with this study as the outcome measures were different. There were also differences in the techniques as in this RCT, patients were operated on with local anaesthetic but on the BSUG database only 13.9% of patients had local anaesthetic for RPT and 30.3% for PUB [213]. There was also a 'top-up' PUB injection given in about a third of the RCT cases. The population of the RCT and the BSUG database who received PUB were likely to be different as the RCT randomised all primary SUI patients to either RPT or PUB but as described earlier the patients in the BSUG database were older and likely to be more co-morbid.

A 2017 systematic review of all types of trials looking at PUB, found subjective success rates ranging from 66% to 89.7% [212] at 12 months. The subjective measures were visual analogue scale, Likert scale, International Consultation on Incontinence Modular Questionnaire (ICIQ), Patient Global Improvement Questionnaire (PGIQ) and Incontinence Impact Questionnaire (IIQ). Although it was not clearly stated in the paper, the reviewers defined "success" as cure or improvement, rather than complete cure. The results from the BSUG database for PUB of 59.2% for PGII or 74.3% with cure/improvement of SUI are on the low side compared to the range of 66-89% found

in the systematic review [212]. They found that objective success rates for PUB were less well documented than in studies about mesh mid urethral tapes but ranged between 25% and 73%.

Analysis of the DugaBase, which is the Danish urogynaecology database, found lower success rates (cure in 29.8% and no leakage in 9.1%) for PUB [94] than the above review [212]. The results for this series found a cure rate of 28%. It is likely that this BSUG analysis and the review of the Danish database reflect a more accurate picture of real-life practice because these were not trials and do include a wide range of surgeons and centres with a non-selected population. This is an example of where an RCT gives the best possible outcome and the results from two database studies (DugaBase and BSUG) shows how the intervention performs in real life again in a more heterogeneous, non-selected population [171]. This may alternatively suggest that there is a need for greater expertise in clinicians performing PUB as the trial results were better and this may relate to clinicians in the databases being less skilled for this technique compared to the trial clinicians being experts.

The population, entered onto the BSUG database, receiving PUB moving forward will likely become younger than in this study due to the lack of availability of mesh tapes, and the workforce more skilled and this might suggest that there would be improved outcomes closer to the Mikkola study [13, 211]. However a small retrospective study looking at this has not shown a difference in success defined as cured or improved of salvage 75% (n=28) and primary bulking 67% (n=86) [50].

Outcomes in patients with pre-operative OAB did not reveal any differences between the procedures. Patients' symptoms of OAB do improve following treatments for SUI despite it not being designed for this. The mechanisms that lead to the symptoms of OAB are not fully understood and it is likely to represent the final common pathway of various pathologies which, would explain the variation in response. One explanation was offered by Petros, with integral theory, where it is postulated that stabilization of the pubourethral ligaments by the RPT rebalances the pressures with in the pelvis and reduce urgency symptoms [214]. A second explanation can could be that this is a secondary psychological phenomenon where reduced anxiety, due to reduced likelihood of a stress leak, decreases the recognized symptom of secondary or adaptive OAB [215]. As patients are no longer worried about stress leaking, they no longer need to void so frequently to keep their bladder empty to reduce the possibility and volume of leakage. In the small 29 patient series by Mitsui of AFS, 7 out of 17 patients with pre-operative urgency found their urgency was cured post-operatively [204]. A higher rate of cure of OAB was seen by Liu et al with 50.5% of cases with pre-operative OAB experiencing resolution after MUS [64]. In this BSUG study, it was not possible to see what medical treatments patients may have received for OAB symptoms. Linkage to electronic medical records would allow more medical information to be included in the analyses to ascertain other less obvious differences in patient characteristics such as diabetes, heart conditions, recurrent UTI or metabolic syndrome [48] which are all known to be related to OAB.

In patients without pre-operative OAB, higher percentages of patients undergoing AFS and colposuspension reported new symptoms of OAB compared to RPT, however this did not reach significance. A significantly lower odds of developing new OAB was seen

following PUB compared to RPT. As one would expect the more obstructive procedures were associated with a greater risk of post operative OAB. The mechanism behind worsening OAB following a RPT may be due to a severe sphincter weakness pre-operatively meaning that prior to surgery the bladder could not naturally fill sufficiently to reach a stage where the bladder was full enough to create OAB as the sphincter was too weak to retain the urine. RPT insertion means the outlet resistance increases and so the bladder fills sufficiently to lead to OAB symptoms whereas prior to the procedure stress leakage would have meant the bladder could not fill. Published literature suggests de novo OAB rates following TVT are between 0.8-25.9% [3, 64, 68, 97, 203, 216]. The wide range is thought to be more due to the variety in definitions of OAB rather than actual differences.

Complications

Bladder injury rates were similar in RPT, AFS and colposuspension with, significantly lower rates in PUB. Return to theatre was rarely reported for RPT and colposuspension and not reported for AFS or PUB. There was a significantly lower odds of return to hospital and readmission to hospital following PUB compared to RPT. There was a significantly higher odds of return to hospital and readmission to hospital following AFS. Data on complications and return to theatre and hospital are not well documented in the literature, most likely because it is a low frequency complication meaning the numbers seen in trials cannot be meaningfully analysed and this highlights where larger data sets become more useful. This is important for women to consider when planning their recovery and considering carer and career responsibilities. This can have financial, economic and personal consequences.

Secondary analysis: Comparison of patient characteristics within treatments

With regards to the effect of patient characteristics on outcomes, several features were apparent. Broadly speaking, increased age, increased BMI, DO in the UDS, bladder damage and repeat surgery led to poorer outcomes. A non-consultant grade operator was more likely to cause bladder damage and if this did occur the patient was more likely to return to theatre and return to hospital. Age also increased the odds of bladder damage and returning to hospital. Increased BMI led to a lower odds of bladder injury in RPT.

Age

Increased age led to less favourable outcomes for RPT and colposuspension and increased post operative OAB. This has been seen in other studies [59-69, 76, 86, 217-220] including the SISTEr trial [221]. Age did not appear to affect PUB which may make this a more attractive option for the elderly population. What cannot be evaluated from this work is whether if those people were operated on at an earlier age would this have a protective effect on the deterioration of their bladder or would the outcomes have been the same with an earlier operation and on-going deterioration post intervention. This would be difficult to assess and require a complex longitudinal study rather than a cross sectional design. It would be interesting to establish whether it is a natural progression of worsening bladder function or whether the intervention occurring at a later age increases the risk of failure.

For colposuspension, there was a significant increase in odds of bladder injury with increasing age and a biologically plausible explanation for this may be that the tissue is less well oestrogenised so increases the risk of injury to the bladder during the

dissection and there are changes in the tissues with a reduction in collagen as part of the aging process.

With colposuspension and AFS, it was not known whether the increased returns or readmissions to hospital with increased were planned or for urological reasons. Increased age and increased co-morbidities have previously been associated with a higher chance of non-urological complications in sling surgery [222].

BMI

Increased BMI led to decreased odds of successful outcomes in RPT, and this has been seen by others [59, 63, 67, 69-73, 218]. However analysis from the DUGAbase [223] and others [224-227] found that there was no difference in subjective outcome between different groups of BMI. The highest BMI category in the DUGAbase study was BMI >35, with 6% of the participants in this group compared to 11% in this study and they compared it in groups rather than doing a continuous method. Other studies are limited by a lack of women in the severely obese categories and are thus less relevant to the Western populations. The prevalence of obesity in adults in England between 1993–2014, rose from 14.9% to 25.6% and continues to increase [228]. The use of midurethral slings in the severely obese population has not been studied on a large scale or with the very high levels of BMI. As obesity becomes more of an issue it will be important to have knowledge of outcomes. Conventionally such a study would be problematic, but a database is ideally suited for this, as numbers of women with high BMI would be low in an RCT (or these women even excluded).

Obesity is a modifiable patient characteristic, so it is vital clinicians can inform patients about its negative impact on outcomes of SUI surgery, providing appropriate information and thus empower lifestyle changes to alter risk factors. The association between urinary incontinence and increasing BMI is well recognised [36, 44-46, 48] and patients should be informed of this as if BMI can be reduced then surgery may be rendered unnecessary [36, 47, 229]. If surgery is still required, then logically the outcome should be more successful, although this has not been proven and is an assumption: no studies were found assessing the effect of weight loss prior to surgery. Cost wise, and ethically, there is a question as to whether treatment should be offered to a patient if they have not attempted to change a modifiable patient characteristic that is likely to improve their condition. Conversely, it could be argued that it is not justifiable to withhold treatment and that treating SUI may enable weight loss therefore improving health overall, or indeed whether this ultimately leads to a resolution of their OAB symptoms. A further problem is BMI on its own is a crude metric. Some patients merely have a high BMI whilst others have metabolic syndrome with more wide reaching implications [48].

As BMI increases there was a significantly decreased odds of the patient suffering a bladder injury following RPT which has been seen in other analyses [102-104]. The reason for this may be that more peri-vesicular fat with increased BMI so was protective of bladder injury. Also in the literature no difference in complication rate was seen in increasing BMI in a retrospective cohort of 688 women however this may be due to the smaller numbers [67].

PFMT

Pre-operative PFMT showed no significant impact on outcomes and there have been no definitive results seen in the literature regarding the outcome of surgery related to previous PFMT [98-100]. There are lot of unknowns regarding PFMT and the BSUG database. There was no information on whether PFMT were self-directed or supervised by a physio. There was no information on patient compliance and how effective the PFMT were such as comparative muscle strength [230, 231]. A longitudinal disease-based database available to physiotherapists or linking the database to electronic patient records could enable this to be captured. NICE guidance recommends that PFMT should be offered to all patients [38]. Some patients decline or not be offered PFMT and proceed straight to surgery which may lead to bias.

Pre-op UDS

Pre-operative urodynamics provided useful insight into outcomes, with DO being associated with poorer outcomes for RPT. This is important for counseling and managing patient expectations. There has been a paucity of research, on the surgical management of mixed urinary incontinence, but poorer outcomes following RPT with pre-operative DO or mixed UDS has been seen in other studies [64, 68, 73, 76, 83, 96, 219, 220, 232]. The conclusion from these authors was that there was good evidence to perform an RPT to cure the USI but urodynamics would help with patient counselling.

Grade of operator

Non consultant grade of operator increased the odds of a bladder injury which is likely to be explained by being on a learning curve as this has been seen previously in

inexperienced surgeons [102]. Non-consultants also experienced a significantly higher odds of return to theatre following RPT and this may be related to the previously noted increased rates of bladder injury in non-consultant grades although it was not confirmed that these were the same patients, and this analysis does not give information on the reason for the return. There were no significant results for PUB, AFS and colposuspension as there were not many non-consultant doctors performing these surgeries.

It is not practical to stop trainees performing surgery but training models should be considered prior to operating on patients [196] and only those trainees with a plan to have female continence in their consultant job plan should perform these procedures to avoid unnecessary harm to patients.

Bladder perforation

Bladder perforation as a variable (not an outcome) leads to poorer outcomes in RPT. The physical presence of a perforation itself may not be the cause of a worse outcome. Possible explanations include that a surgeon who is less skilled at performing the operation is more likely to perforate, the impact of the patient being told that there was a complication and therefore have the opinion that the operation worked less well or that when the RPT is repositioned following a perforation the tape is placed differently to avoid a second perforation, and this may lead to a less beneficial outcome. Bladder injury also leads to a significantly higher odds of return to theatre and hospital. This is very useful if a bladder injury has occurred to be able to inform the patient that they are more likely to need to return to theatre or hospital so they can be mentally and physically prepared.

Repeat SUI surgery

When the surgery was a repeat procedure, the odds of success were reduced for RPT, PUB and colposuspension and an increased odds of bladder injury was seen in RPT. Previous colposuspension has been seen in another review to increase the risk of bladder injury [102]. Reduced success rates have been noted previously with repeat surgery [59, 60, 72, 75, 78, 79, 233, 234] and may be due to scarring, nerve damage during periurethral dissection, or it may be that those patients had worse SUI with more severe neuromuscular compromise [59] leading to the poorer outcome including requirement of secondary surgery. It is important for the first surgery to be as good possible as explained in the Getting It Right First Time (GIRFT) programme [181].

Implications for clinical practice

This information can be used to aid decision making and allow patients to make informed decisions about treatment options and life-style choices. Bespoke patient counselling is important prior to SUI surgery as the aim is to improve quality of life which is firstly dependent on the patients' ideas, concerns and expectations and secondly difficult to quantify compared to a simpler outcome such as a numerical change of a blood test seen in other conditions.

The information from the primary multivariable analysis comparing treatments can be used to help women decide what treatment is more suitable to her wishes. If a woman is requesting a 'cure' of their SUI symptoms, a RPT, AFS or colposuspension is likely to be more appropriate however a lower success rate, if coupled with a low complication rate, is not necessarily undesirable and must be put into context for patient choice. It has been shown that if counselled fully patients are more likely to opt for the least invasive treatment [184] and it is important that women are given all the options and for clinicians to be aware of the patient's expectations [235]. A study looking at patient perspectives of PUB showed that women do not necessarily expect a complete cure for urinary incontinence, rather they want to improve and have reported that "becoming dry was wishful thinking" [236] and as such, patient related outcomes or goals are increasingly important as part of the assessment of outcome.

Rates of return to theatre, return to hospital and readmission to hospital are particularly useful for patients counselling as this has not been widely reported previously as trials are less likely to report this type of information and the numbers on the BSUG database mean that this is more meaningful with large numbers. If a patient is at high risk of anaesthetic complications or lives rurally, an increased risk of return to theatre or return to hospital may be more impactful and this study can help inform this choice.

Patient choice, particularly in functional surgery, is paramount and this, combined with concerns over mesh complications and the Montgomery ruling [237] suggests patients should be informed of all suitable options.

The information from the secondary multivariable analysis which studied how patient characteristics affected outcomes in each treatment can be used to temper expectation in likely outcomes. This analysis should not preclude older patients with high BMI from receiving interventions, as the success rates for these groups were still high, and patient choice is important, but it must be reinforced that bespoke patient counselling is of vital importance to ensure patients are aware of the lower success rate as per the Montgomery ruling [237]. From this analysis clinicians should be aware that for RPT, for every 10 years increase in age there is a 17% decrease in odds of positive PGII, 19% decrease in odds of positive result for cure/improvement of SUI and 20% increase in odds of developing new OAB following a RPT. For every point increase in BMI there is a 5% decrease in odds of positive PGII, 4% decrease in odds of cure/improvement of SUI and 7% decrease in odds of bladder injury. If the UDS included DO compared to 'normal or no UDS' the patient has a 49% decrease in odds of positive PGII, and 35% decrease in odds of cure/improvement of SUI. If a bladder injury occurs the patient has a 43% decrease in odds of success with regards to PGII, and 62% decrease in odds of cure/improvement of SUI.

Patients and clinicians differ in how they view success and failure [42] and only the patient knows how acceptable a complication or side effect would be to them. Women must be informed of the personalised risks and in context with informed consent, these lifestyle alternatives should also be personalised to comply with the Montgomery ruling [237].

Strengths of this analysis

Full strengths and weaknesses of the BSUG database are found in chapter 5 of this thesis.

This dataset is larger than others in the current literature and has been performed on a national level. Rates of return to theatre, return to hospital and readmission to hospital have not been well studied as this data is often not collected at trials and it is rare for this to happen so the larger numbers seen in the BSUG database mean more meaningful conclusions can be taken from this. This is unique due to the large data set.

Limitations of this analysis

The results must be viewed with cognisance of the weakness that there is incomplete data and no validation. Missing data may be because healthcare professionals are not able to see patients back in clinic as there is limited funding for seeing “routine” follow up in clinic with service demand prioritising getting new patients into the system and the rationale is that if patients are not satisfied with the result the GP will re-refer them. An automatic electronic outcomes questionnaire may improve this.

The completion of return to theatre, hospital and readmission to hospital had poor response rates and this may be due to two reasons. The database is commonly completed just after the procedure which means if a complication occurs in the theatre, such as bladder injury, it is likely to be completed as reflected in low missing data for this point. However if there is a return to theatre, return to hospital or readmission to hospital it would not be captured on this initial completion of the database. This requires the operating clinician to be aware of the complication, and to open and

complete the database at another time. This would be improved if the database was linked to the EMR or for a more pragmatic solution, the surgical morbidity meeting could trigger an event as a reminder to the clinician to enter this onto the database. This could be improved by an automatic reminder being sent from the database to the clinician that there is missing data. In this study missing data has in part been overcome using the multiple imputations.

A further limitation is that there is inherent bias in any surgical database as these are the patients that feel their condition is bad enough to require surgery. These patients are likely to have more severe disease than those who opt for conservative measures. To overcome this, a disease, or patient, database would be required, which would progress through the patient journey from presentation, through conservative treatments, with regular completion of validated questionnaires to assess the impact of each intervention. This would allow comparison of disease state at the time of decision making and surgery and post intervention.

Current studies have many different outcomes measures so are difficult to compare so a core set of outcome measures for each condition should be considered to allow follow up and international comparison of routine clinical care.

The BSUG database has no information about comorbidities or medications. A database designed where the clinician was responsible for entering too many data points becomes too burdensome and require significant help in data input or additional functionality to link to medical records to allow this.

The lack of internal and external validation reduces the validity of the findings.

Conclusion

This multivariable analysis using a large national database found that rates of positive outcomes for PGII and SUI were similar following RPT, AFS and colposuspension and the odds of a positive outcome of PGII and cure/improvement of SUI was significantly decreased for patients who underwent PUB. In patients without pre-operative OAB symptoms, AFS and colposuspension had the highest rates of developing new OAB symptoms, followed by RPT and a significantly decreased odds after PUB. PUB also had significantly decreased odds of bladder injury compared to RPT. Patients who had AFS had increased odds of returning and being readmitted to hospital compared to RPT. Conversely patients who had PUB had decreased odds of returning and being readmitted compared to RPT.

For RPT, decreased odds of reporting a positive PGII and SUI was seen with increased age, increased BMI, detrusor overactivity and intra-operative bladder injury. Increased odds of new post-operative OAB symptoms were seen with increased age. Odds of bladder injury increased with a non-consultant grade operator and decreased with increasing BMI. Increased odds of return to theatre was seen with non-consultant grade operator and bladder injury. Increased odds of readmission to hospital was seen with bladder injury. For colposuspension, increased age led to decreased odds of a successful outcome for SUI, and an increased odds of bladder injury, return to hospital and readmission. Repeat procedures led to decreased odds of a positive PGII and cure/improvement of SUI for retropubic tapes, bulking agents and colposuspension. An increased odds of bladder injury was seen with RPT performed as a repeat surgery compared to done as a first procedure.

This large national database has been used to establish outcomes and complications in routine clinical practice and quantified the effects of different surgical and patient characteristics on these outcomes. This information should be used in bespoke counselling to encourage personalised medical decision making. Analyses were limited due to the pre-determined fields recorded in the database. Missing data is a limitation and would be improved with a validated database with mandatory fields to include all procedures audited against hospital coding.

Recording of outcomes is vital to improve patient care but comparisons between studies is challenging as there is no core outcome set to unify data collection. We strongly recommend the use of mandatory, standardised prospective data collection to enhance understanding of outcomes of surgical procedures.

Chapter 4: Clinician perceptions

Introduction

The BSUG database is not used by all BSUG members, and this contributes to bias which is currently a major flaw of the database. BSUG estimate, using HES data, that from April 2008 to March 2017, 40% of continence procedures in England were captured [126] and from April 2017 to March 2019 the estimate was 60% [22]. Similarly, the IUGA database, based on the BSUG database, was launched in 2017 [127] and has 294 international users signed up with just 4496 procedures entered (communication with IUGA April 2022). Database use is recommended by NICE [12] and NHS England [116-118] and reasons for lack of engagement with the database need to be explored.

Results from questionnaires performed by the BSUG database committee and the IUGA Surgical Database Special Interest Group (SIG) were made available for this work. Open ended questions formed part of the questionnaires, which were suitable for qualitative analysis. Qualitative analysis was first developed as a technique in the 1950 and 60s [238, 239] and uses codes, concepts and themes identified within text to condense and gain better understanding large amounts of written information. There are several methods of analysis for qualitative research [240-242] including interpretative phenomenological analysis, discourse analysis, hermeneutics, grounded theory, ethnography, and content analysis.

The questionnaires were not designed to answer a specific research question and had flaws as described below. However, it was felt important to include this information in the thesis to attempt to gain an understanding of clinicians' views about the BSUG

database to support further recommendations about its development. Due to restrictions on email contact with members of BSUG and IUGA no further questionnaires specifically developed for this work could be distributed.

Methods

The first questionnaire was an anonymous questionnaire (appendix 13) sent from the BSUG administrator to BSUG members in 2016 (number unknown). A single email with no reminder was sent. The timeframe to reply was 17 days and the questionnaire was accessed by following a link to survey monkey [243]. The questionnaire was designed by the BSUG database committee, and the raw data of the answers were provided to contribute to this thesis to help explain the poor uptake of the database. The survey had 8 questions focussing on how information gathered on the BSUG database should be used. The question of relevance to this thesis was regarding what would encourage clinicians to enter data onto the database. The raw data were provided.

The second questionnaire was again an anonymous questionnaire (appendix 13) sent to IUGA members in June 2021 (n=10,624). A single email was sent from the IUGA administrator, with no reminder and 28 days to respond. The questionnaire was designed by the IUGA Surgical Database SIG, to establish suitability of existing national urogynaecology databases, such as the BSUG database, as well as the need for the IUGA database [127]. The questions of interest were whether the BSUG database was fit for purpose and whether there was a need for the IUGA database. Only answers from UK respondents were included. The raw data were provided.

The approach for qualitative analysis was a conventional, conceptual content analysis. Inductive reasoning was used for the analysis as this was to gain new conclusions rather than test a previous hypothesis which would have been deductive reasoning. Phases used were decontextualization, recontextualization, categorisation and compilation [244]. Decontextualization involved reading the text multiple times during which codes were identified, also known as a “meaning unit”. Codes were generated during analysis and the text was coded for existence, rather than frequency, of a concept. Coding was performed by hand not computer programme. Two types of codes were used: manifest or semantic, and latent. Manifest or semantic codes identify surface meaning of the data using the words written in the text. Latent codes extends the analysis to attempt to interpret the underlying meaning of the text, with the awareness that this is a more subjective analysis [245]. During recontextualization, the text was reviewed to ensure no codes had been missed and no important text had not been assigned a code. Following generation of the codes, themes were generated in the categorisation stage and the compilation phase involved analysing and writing up the themes.

Results

BSUG database questionnaire

There were 131 respondents for the first questionnaire sent to all BSUG members in 2016 (denominator unknown). There were a range of database usages reported by respondents including ‘registered routine data entry including private practice’ (23, 17.5%), ‘registered routine data entry NHS only’ (48, 36.6%), ‘registered regular use’ (29, 22.1%), ‘registered very limited use’ (14, 10.7%), ‘registered do not use’ (10, 7.6%) and ‘not registered do not use’ (7, 5.3%).

Details were given by 39 people on what would encourage them to enter data on the database.

The semantic themes generated included logistical barriers, bias, clinician fear and prospects for the database. A latent theme of frustration was identified.

'Logistical barriers' to the database, was the theme with the greatest amount of information and this was divided into the initial set up of the database and the day-to-day usage. Clinicians reported difficulties with initial set up of the database due to trouble gaining Caldicott approval [133] and developing appropriate passwords with a report of a need for it to be "more user friendly". The ongoing day to day obstacles were more numerous. Time was a major factor, where clinicians reported challenges with inputting operative information due to lack of time in theatre, recording outcomes due to a lack of time in clinic and chasing patients who did not attend planned follow up clinics due to a lack of time in their job plan. Personnel in clinic was another concern, as respondents stated it was difficult to collect outcome data with different junior staff conducting follow up appointments. Administrative support was noted to be a barrier with regards to outcome recording, data inputting and chasing non responders. Ease of access to the database was a hurdle that was identified where respondents struggled with it only being available on NHS computers and felt it would be improved with access from home, in private practice and on a mobile phone app. Patient consent was identified as a troublesome area but with no further information regarding this. There was a perceived financial obstruction with regards to funding and a suggestion that the database should be freely provided without BSUG membership.

Bias was identified in several areas. Respondents stated that the database should be mandatory and compulsory for anyone performing the surgeries. A quote from a respondent described this: *"Gynaecologists should only use BSUG database if all consecutive cases are included. This should be a mandatory requirement before registration and checked at accreditation or spot audits."* The method of outcome data collection was another area of bias identified by respondents and stated that this should be in isolation from the operating surgeon either by a secretary or centrally arranged via electronic automated questionnaires. With a quote from a further respondent *"It cannot be used as an effective audit tool unless data entry is mandatory and entered by support staff rather than clinicians"*.

Fear from clinicians was identified as a barrier to the use of the database. A quote from another respondent said: *"People use lots of excuses for not using the database. My feeling is that much of this is a fear of publicly stating workload and results."*

Prospects for the database was identified as a theme which included desired future benefits of the database with ideas to encourage clinicians to enter data. A desire to know individual outputs and to be able to compare outputs with other, particularly tertiary, units was identified along with an opportunity to share experiences. An aspiration to develop trials on the database was reported but with no further clarification of how this would be achieved. Rewards such as funding/prizes/grants for top 10 contributing units was suggested.

A latent theme of frustrations was identified by delving deeper into the ways clinicians answered the questions. The evidence for this was in the language used where

clinicians described needing to “work hard to collect data”, “trying to get support”, “need help” and “struggle”. It appeared to be evident that respondents did support the idea of databases and outcome collection but felt frustration that the current package was not fit for purpose.

IUGA database questionnaire: Regarding BSUG database: UK respondents

The IUGA questionnaire generated 313 respondents from 71 countries listed in appendix 13. There were 40 respondents who stated they were from UK.

Members of IUGA were asked about whether their national database was fit for purpose and the 40 UK answers were identified and analysed. 33/40 (82.5%) respondents reported that the BSUG database was fit for purpose and 5 reported it was not (2 unanswered). There were a range of positive and negative responses explored in this analysis with the full answers listed in appendix 13. The positives of the BSUG database identified were that the database was comprehensive, in-depth, and covered all procedures, including follow up outcomes. It was reported to be helpful for appraisals, was long standing and well recognised. The negative themes identified in this question were similar to those themes described above including bias and a desire for a mandatory database with compliance checks and by having the outcome data collection independent to the clinical team.

IUGA database questionnaire: Requirement for IUGA database: International respondents

Members of IUGA were questioned about the necessity of the IUGA database which is based on the BSUG database. Respondents who were positive about the IUGA database expressed broad sweeping statements such as “it is needed” and that it would “improve all aspects”. They described the potential of what could be achieved without considering any logistics. Respondents with negative comments tended to be much more specific about smaller logistical problems.

The positive themes generated, which illustrate how respondents thought the IUGA database could benefit the urogynaecology community, included increased information sharing, big data with research, and standardisation (unifying criteria) with evidence-based practises and guidelines.

It was felt the IUGA database could facilitate *increased information sharing* by demonstrating what surgeries were being performed by different clinicians, the indications, the outcomes and complications including long term follow up. There was a sense that a database could help clinicians to learn from their peers regarding differing practices and sharing of experiences and knowledge to help with training. A benefit that respondents saw was to give a better picture of international global information to understand variation of managements worldwide and how urogynaecology was run in each country. The information people reported to be interested in was trends, epidemiology, global surgical burden, and disease prevalence so they could plan training. It was noted that it had the potential to facilitate early detection of issues related to poor outcomes or complications.

Respondents were enthusiastic about big data and how this could contribute to research. Respondents reported that the large numbers gathered from an international community would have “better authority” than smaller databases. It was reported it would be good for research but in a vague way without qualifying this further. There was a comment that multicentre studies would be able to be facilitated.

Respondents reported that the database would allow standardisation of care, evidence-based treatment with development of evidence-based guidelines and management pathways without giving further qualifying information on how.

The negative themes centred around the logistical challenges and bias.

Logistical challenges identified for the IUGA database were that due to the huge numbers of countries involved there would be too much variation in practice, jurisdictions, regulation, approaches, and that a database and data collection would be difficult to implement and manage. There were concerns about ownership of the data, privacy and sharing of national data. There was concern regarding doubling up of data entry meaning information would be entered into patients notes and then again on the database. Patient consent was identified again as troublesome without further elaboration.

Concerns with *bias* was again noted for the IUGA database as it had been for the BSUG database. It was expressed that the database should be mandatory, validated, without selective entry. It was noted that not all pelvic floor surgeons were members of IUGA so it would not be a complete cohort of all surgeries performed. There were

concerns about transparency and accuracy and a requirement to eliminate outcome reporting bias by being independent of the operating clinician. There were concerns about validity and that the results would be uninterpretable.

A final theme was about what clinicians felt was important in the IUGA database and how to optimise functionality and utility of the IUGA database. It was suggested that there could be national databases with a template of a mandatory dataset which contribute to an international databank and additional data points could be added if required by each country. It was proposed that IUGA could guide and give technical support with a database committee to compile results with feedback. There was a hope for a universal tool, uniform format and standardised reporting.

Discussion

It was important to analyse this information, as the BSUG database is a non-compulsory database which has led to selective uptake by clinicians. The answers gave some reasons for the incomplete engagement with the database.

Clinicians identified many logistical barriers to the BSUG and IUGA database however limited resources may make these difficult to overcome. With regards to the initial set up and data entry BSUG have produced a series of video clips [246] to assist clinicians with this. The problem of doubling up of data could be eliminated if electronic notes could be aligned with the database however currently there is not a universal electronic medical record in the UK, and this would be much more of a challenge with an international database. Time and administrative support were identified as a challenge however with the current financial constraints faced by most NHS trusts these problems will not be easy to overcome. Ease of access to the database could be improved by enabling appropriate secure log on either on non-NHS computers or mobile phone via an App.

The concerns regarding bias are difficult to eliminate with the current set up of the database. The process of making the BSUG database mandatory cannot be achieved on a societal level and would require intervention from a governmental organisation, to enable a similar set up to the orthopaedic or cardiac registry [145, 153]. This may occur with the introduction of the pelvic floor registry [247]. Presently outcome data is often collected by the clinician which was recognised as a source of bias. Electronic patient questionnaires were identified as a way to reduce this bias, however, again take resources to enable. The additional benefit of these would be that, once set up,

they would streamline follow up with automatic regular reminders to patients leading to increased efficiency, eliminating many logistical challenges described above.

Positive points regarding the BSUG database revolved around a desire to know outcomes and to be able to compare these with other people. Respondents felt the database was helpful for appraisals. It was reported that there was a full coverage of inputs and outcomes.

There is support and underlying enthusiasm for an international database however, the responses from these questionnaires demonstrate that a truly international database would be very difficult to achieve in view of differing data protection laws and other legislation. Respondents had ideas of how an international database could function, for example, with a core input and outcome set determined internationally and included in each national database. Each country design and legislate their own database, with a central office at IUGA for analysis. Mandatory completion and validation would remain an issue and may be dependent on the government of individual countries. With so many ideas, it is clear there is enthusiasm for the international database, all with slightly different focusses. It would be important that the design of such a database were determined by an international consensus approach including all stakeholders, particularly patients. This would enable all interested parties to have input into the database while ensuring that data fields were appropriate, not overlapping and the database was not impractical either in length of complexity.

Respondents who described the positive statements of improving standardisation of care and developing evidence-based guidelines maybe had not considered the logistics of implementing this and the resources required. A database would be unlikely to do either of these things in isolation but would rather facilitate further work which could audit current standards and guidelines and then create standards which could then be re-audited using the database. This would then facilitate standardised comparisons. It would be important that if a new international database were launched that users were aware of its potential uses and limitations.

Validity

As these questionnaires were not specifically designed with an output in mind there are significant limitations. Therefore, the usefulness of the subsequent data is limited in terms of the analysis possible. However, there has been no previous work undertaken to understand clinicians' views regarding the BSUG or IUGA database and thus this represents an opportunity to understand some of their views and concerns but also inform potential future research in this area.

The response rate is not known for the BSUG questionnaire as the denominator (number of people sent the questionnaire) was not recorded. The response rate for the IUGA questionnaire was low. There were no reminders sent for either questionnaire which means that the response rate was not optimised. The response rate is key to external validity and therefore the generalisability cannot be guaranteed across the whole of the societies. This was because there are a lot of survey requests and the BSUG committee do not want to overload the memberships. Greater rates of return can be achieved by offering incentives and more reminders.

These surveys are from a self-selected group which may bias results. To improve validity, questionnaires would be sent to all gynaecologists, rather than selecting BSUG/IUGA members as information from non BSUG/non IUGA members has been excluded.

As the questionnaires had already been completed there was nothing that could be done regarding set up. The questionnaires could have been improved by deciding on the research questions, aims and objectives to inform the design of the questionnaire.

The questionnaire and questions should have been designed with a qualitative researcher to ensure that the aims and objectives would be answered. The questionnaire then should have been piloted to test that validity and usability of the questionnaire. A well-designed questionnaire would use a combination of open and closed questions. Closed questions ask for a specific response selected from pre-ordained answers. It is beneficial to avoid agree-disagree responses as this can be too divisive meaning some people may not be able to respond at all. It also reduces quality of responses compared to item specific response options [248] and it has been shown that there is a tendency for people to agree with an item regardless of its content [249]. It is better to use verbal options, such as 'strongly agree, somewhat agree, neither agree or disagree, somewhat disagree and strongly disagree' and five appears to be the optimal number [250, 251]. Open ended questions allow much more expression and expansion from the respondents and another instrument, the 10 words question, [252] asks for 10 single words as an answer which could be developed into this questionnaire to be 'write down up to 10 words that describe the perfect database'.

Other considerations particular to qualitative analysis would include assessment of external and internal resources. External resources include funding, time and evaluating the population from which to gain the informants. Internal resources relate to the knowledge and ability of the researcher and an importance of taking into account pre understanding and possibility of bias introduced due to the researchers interpretation [244]. The aim should be considered, and this should not be too broad otherwise it is not possible to gain the depth of analysis which is useful. A decision about the sample size required. There then needs to be a choice of method of data collection which include interviews, questionnaires, observations of situations or

pictures and films. There can be potential issues with gathering data as respondents may have different meanings for words, not tell the truth or not be able to explain themselves. Also if there is requirement for transcription some nuances can be lost during this process. In this situation a questionnaire was available and had more information been required interview of supporters of the database and those who did not endorse it may have added more information. Then the data analysis can occur.

Due to the small size of text data for analysis, reliability and validity of the coding was not assessed [253].

Clinical/research implications

There is enthusiasm for the use of a database among clinicians but it is clear that to increase engagement with the database modifications are required. How the database will be modified will depend ultimately on the purpose of the database. This will be for the society to determine but this questionnaire would guide them to see that elimination of bias and ease of use are two main drivers for support.

Future research

Future research should involve further qualitative research and formation of a consensus as to the purpose of the database. Focus groups with all stakeholders (e.g. clinicians, patients, specialist societies, NHS) would be valuable. The themes identified in this chapter could be used as a basis for the interview.

Conclusion

Some clinicians have identified the BSUG database is not fit for its current reported purpose and therefore, there is a feeling of frustration among users with a lack incentive to complete it. As the situation develops in the UK and the likelihood of an alternative pelvic floor registry [247] being used increases, the future of the BSUG database is not clear. From this questionnaire, a suggested is a mandatory database with internationally agreed core inputs and outputs, governed by individual countries or societies with an over-arching advisory role from IUGA.

The validity of the findings from these questionnaires is unknown due to the poor response rates and small sample sizes.

Chapter 5: Discussion

This thesis has demonstrated that the BSUG surgical database can be used to determine and compare outcomes and complications following RPT, PUB, AFS and colposuspension in the management of stress urinary incontinence. It has also been shown to be possible to identify patient and surgical characteristics that affect outcomes and quantify effects by which they do. The questionnaire has enabled an understanding of how the database is perceived by clinicians and some of the problems identified by these clinicians. The process of this thesis has allowed an appreciation of the strengths and weaknesses of the BSUG database and its suitability for on-going use as a clinical database and its appropriateness to be used to develop a prognostic model.

Summary of findings

The initial pilot analysis (chapter 2) analysed RPT and PUB as these were the most common procedure at the time of data acquisition prior to the mesh pause. This work demonstrated that RPT had high success rates for PGII and for cure and improvement of SUI symptoms with a significantly lower percentage of patients reporting a positive outcome with PUB for those procedures entered on the BSUG database. In patients without pre-operative OAB, significantly more developed new OAB following a RPT compared to PUB. Patients who underwent RPT were significantly more likely to return and be readmitted to hospital than those who underwent PUB. Standard complication rates were found to be low for RPT and very low for PUB.

The pilot study considered bladder perforation in more detail. Bladder perforation rate was calculated as 3.5% for RPT with no bladder damage reported for PUB. A funnel plot demonstrated the variation in bladder perforation rates between centres entering data on the BSUG database. The highest volume centres were all out with the funnel and the reasons for the high rates could be attributed to large number of procedures being performed by non-consultant grades, who have a higher perforation rate and vice versa with low rates having low numbers of non-consultant grades.

The initial pilot also showed that pre-operative patient characteristics altered outcomes in RPT on the BSUG database, with significantly lower success rates in patients with higher BMI coupled with an increased rate of worsening or developing new OAB symptoms in the higher BMI groups. Pre-operative UDS with detrusor overactivity led to worse outcomes with RPT and bladder perforation reduced cure/improvement of

SUI for RPT. This information was taken forward into the multivariable analysis which included two additional SUI procedures of AFS and colposuspension.

The conceptual long term aim of this work was to develop a risk calculator to allow personalised prediction of outcomes and complications for women planning a retropubic tape and to establish whether this could be achieved using the BSUG database. This work was postponed due to the UK national pause on performing mesh tapes. When the mesh pause occurred, it was decided to broaden the procedures included in the analysis to incorporate AFS and colposuspension as these would need to be included in any future prediction calculator. It was necessary to use multivariable analysis to ensure that the findings in the pilot analysis were still valid when all available variables were taken into account.

The primary multivariable analysis, comparing the four treatments (chapter 3) showed high success rates of success in PGII and cure/improvement of SUI for RPT, AFS and colposuspension and a statistically significantly lower odds of success for PUB. In patients without pre-operative OAB symptoms, patients undergoing PUB had the lowest odds of developing de novo OAB. Bladder injury rates were similar in RPT, AFS and colposuspension with significantly lower odds in PUB compared to RPT. There were reduced odds of return and readmission to hospital following PUB compared to RPT, and increased odds with AFS.

The second multivariable analysis, assessing characteristics that affected outcomes of individual treatments (chapter 3), demonstrated that for RPT, the odds of success for PGII and SUI was found to decrease with increasing age, increasing BMI, any DO

in the UDS and bladder injury. An increased odds of developing new OAB, following RPT, was found with increasing age and a non-consultant grade performing the surgery. For RPT, the odds of bladder injury were increased when a non-consultant grade was performing the surgery and decreased with increased BMI. Bladder injury, and non-consultant grade surgeon increased the odds of return to theatre for RPT. For AFS, there was an increased odds of readmission to hospital with increasing age. For colposuspension, increased age led to reduced odds of cure/improvement of SUI and increased odds of bladder injury, return to hospital and readmission to hospital. Repeat procedures led to reduced odds of success for PGII and SUI symptoms for RPT, PUB and colposuspension. An increased odds of bladder injury was seen with repeat RPT compared to first surgery.

The interpretation of the above findings has to be made with an understanding of the limitations of the database, discussed later in this chapter.

Answers from questionnaires performed by BSUG and IUGA, completed by clinicians, regarding their views about national and international databases (chapter 4) were used to identify reasons for lack of engagement with the BSUG database. Logistical barriers and bias were the main themes generated. There was the recognition that a mandatory, validated, audited database with adequate administrative support to include access outside the NHS system and appropriate patient follow up would improve its functionality. It was noted that the database was comprehensive covering all procedures and that it was reported as being useful for appraisals. A suggestion was made for a series of national databases with a core mandatory data set to be included in very country that could be centrally collected.

Strengths and weaknesses of the BSUG database

The exploration of the data within the BSUG database as performed in chapter 2 and 3, complimented by the views of clinicians in chapter 4, has allowed as assessment of its strengths and weaknesses to compare with the description of a perfect database, described in chapter 1.

Prior to the analysis, it was known that the BSUG database recorded real life clinical practice with a large amount of data and had the potential to contribute to real world evidence. Despite not including all the continence cases in the UK there were still large numbers and as there was no another UK database for urogynaecologists to enter data into, it was the best option to analyse. Analysis has been demonstrated to glean useful information, however further evidence that the BSUG database was not the perfect database described earlier was confirmed.

Strengths of the BSUG database

The BSUG database is longstanding, having been active since 2007 and it is widely used, despite not being mandatory. The variables that can be inputted and the outcomes recorded are simple to obtain without need for “additional” investigations or tests that would not be part of routine clinical practice.

Yearly reports are published on the BSUG website. Clinicians can *report live data* in a clinical setting by generating personal reports in real time.

Clinicians reported that the BSUG database can be used in clinical appraisal. It is required for accreditation with BSUG [254]. For certain clinicians who use it to record their procedures, outcomes and complications it is a good tool.

The large numbers in the BSUG database mean that outcomes that are often not reported in smaller studies can be analysed, such as rates of return to theatre, return to hospital and readmission to hospital.

Weaknesses of the BSUG database

The database is not *"100% completed"* as it is non-mandatory, rather, it depends on self-motivated clinicians, which ultimately has resulted in inconsistent data capture. There are many ways that the data may be missing. Procedures may be entered but one data point, such as BMI, missed. Patients may be lost to follow up due to the patient not attending, or a junior doctor in clinic being unaware of the requirement to complete the database, or not be enough time or administrative support to complete the database. Patients may not give consent to be included in the database. Data from a whole consultants practice may not be included if they choose not to enter data, are a gynaecologist not registered to the BSUG database, or are a urologist. There is no consequence for non-completion and there may be a reluctance to enter a bad outcome. The database is biased toward responders with no recorded denominator.

There is no guarantee of *"accurate validated information"* as there is no process for internal or external validation. The BSUG database does not *"avoid bias"* which can occur on many levels. Missing data is a huge potential for bias. As it is non-mandatory, there may be a difference between the surgeons who "do" vs "do not" enter on the database.

There are difficulties using patient reported outcome measures as an outcome, as "success" is partially dependent on the counselling prior to the procedure. If the patient

is told to expect complete cure, then anything else will be a “failure”, however if the patient expectations are just of “improvement”, then they will count this a “success”. Collection of the outcomes by the operating team may bias the patient in the outcome they report.

There are a variety of timescales and methods of follow up due to individual preference. Current outcomes are short term whereas longer term outcomes are required in view of success as patients are often not fully mobile at 6 weeks so will not have returned to normal activities of daily living [255]. Also, in view of the longer-term complications such as mesh complications which are often not evident immediately.

There has to be *“additional effort by clinicians”,* as data must be entered onto the hospital system and again onto the database. During development of the BSUG database, large amounts of work for the set-up of the BSUG database was done by individuals of the BSUG society, without assistance from the government or any other official channel (PM interview). It was identified that it needed a full admin support group however there was no funding available. This is still the case with individuals spending their own time developing and working on the database and creating reports for the BSUG members.

The *“clear aim”* on the BSUG website states “The BSUG Database is an online tool used by BSUG members to gather surgical data which can be used to develop statistical reports - which in turn are used to improve understanding and standards of patient care” [256] which is not very clear or concise.

The database evidently is not *"endorsed by all stakeholders",* as not all clinicians enter data. The questionnaire regarding the BSUG database has shown that there is support for the database but there are clinician concerns regarding logistical difficulties and bias. Some of the lack of enrollment may be historical as there was significant negativity about the database as it was seen as "*policing in the early days*" (PM interview). The committee felt there was resentment from some members who suggested that the database was only there to "*generate loads of papers out of other peoples' work and this policing had to stop*" (PM interview). There was a feeling that some vocal people did not want their data to be used for other peoples' gain, as they felt it was 'their data'. As such, historically negative emotions have predominated, and some can be very protective over outcomes relating to their patients. Some clinicians feel that when data is being collected it is akin to being "spied upon" (PM interview).

The outcomes are *relevant* as is demonstrated by the high numbers of trials that use them, but there is a need for longer term outcomes, and these should align with a core outcome set so can be compared to other research in the area.

Recommendations arising from this work

How to improve the BSUG database

Factors to improve the BSUG database would be to remove bias by ensuring complete data entry and validating the data. Outcome collection should be improved, and this would require funding and a shift in objectives with full stakeholder “buy-in”.

Incomplete data entry

There have been efforts to improve the uptake of the BSUG database by only allowing accreditation with BSUG if that unit has 90% patient registration and 60% outcomes data completed [122]. However, accreditation with BSUG is also non mandatory. There has also been an effort to improve outcome reporting by adding the percentages of patients awaiting follow up onto the front page of the database when it is opened as an aide memoire to complete data [125]. To improve the amount of data collected per patient, the database could be modified to only allow the computer page to progress if all mandatory boxes were completed. There is the risk of losing the whole patient with this approach if the information cannot be found. This could be improved by an automatic reminder being sent from the database to the clinician that there is missing data. More administrative support is needed. The database should be available to all surgeons who perform SUI surgery and would be beneficial to be available outside the NHS system such as on a secure phone App.

Data validation

Bias could be reduced by regular internal and external *validation*. This has been achieved by the DUGAbase [162] where 200 records selected at random were

examined with 90% agreement between the medical records and DUGAbase in 2011. This would require funding and mandates.

Patient Reported Outcomes Measures (PROM) should be retrieved without contact with the clinical team to remove this element of bias and to reduce the administrative burden, such as by email or phone App to gather regularly timed responses, over longer time periods. This would allow regular day to day clinical practice to run like a huge ongoing trial. The outcomes should be relevant to both clinicians and patients and should have an appropriate time frame. The current outcomes on the BSUG database are short term, and even though it is known that short term outcomes for RPT are likely to correlate well with longer term outcomes based on the TVT follow up data [257], it is important to have longer term follow up in view of outcomes but also in view of the longer term complications such as mesh complications which are not identified in the short term.

If the database could be linked to electronic patient records to gain further information on comorbidities, medication, office evaluation, counselling and decision making could be added without increasing clinician burden. This would rely on there being standardised electronic notes nationally which there are not.

Clear aims and objectives

There is a stated *aim* for the BSUG database as already highlighted. This could be bolder to suggest it requires 100% of all continence procedures to develop robust data to audit, benchmark and gain long term follow up. A clear aim means a database can be appropriately designed at its inception to optimise utility. A clear question should

be defined, and this depends on the focus of the database whether it is merely for recording numbers of cases, or for looking at outcomes, complications, benchmarking or long-term outcomes.

Stakeholder endorsement

A database endorsed by all stakeholders can be challenging to achieve, as there are many stakeholders involved in the BSUG database. Broadly, there are the *users* of the database: the clinicians, and the *consumers*: patients, auditors and researchers. Clinicians could include physiotherapists, nurses and doctors including specialists and GPs. This is a very diverse group of highly educated, informed and often opinionated professionals who are likely to have highly concordant views on a number of data points that should be included, but there are also likely to be data points that some people feel are vital, but others feel could be excluded, so spark debate.

Patients are the other group of stakeholders and again are a diverse group. Patient involvement is crucial in database development as they have lived experience of the conditions and can advise what outcomes are important to them and the preferred methods for collecting them.

Dataset: core outcome set

In an ideal world, the BSUG database would collect all the possible information any stakeholder could ever want but this is not possible in reality, as it becomes too arduous to complete. Conversely, if too many points are left out, the database may lack value and practicality. Data can be enhanced by linking in to other databases

such as CPRD [159] to increase the information without adding to the data burden for the clinician.

A minimum mandatory dataset could be developed for the database with additional points to be included if the individual clinician desires. Ideally this would be agreed worldwide, but it is difficult to homogenize practice and outcomes with such healthcare diversity between countries.

A minimum dataset can be achieved using a Delphi process [137]. Such as performed by The IUGA Special Interest Group for surgical databases, where inputs and outcomes, from existing urogynaecological databases and registries were identified and a modified Delphi process was undertaken to identify a potential minimum core outcome set [137]. A weakness of this was there was no patient involvement.

Currently there is the development of a Core Outcome Set (COS) for SUI by the CHORUS group (An International Collaboration for Harmonising Outcomes, Research, and Standards in Urogynaecology and Women's Health) [258]. This work aims to develop, disseminate, and implement a COS for SUI [138]. The researchers have planned to perform an extensive literature review from RCT to identify potential core outcomes which will be evaluated in an international, multi-perspective online Delphi survey. This will allow outcomes important to all stakeholders, to be reported consistently and comprehensively. They are planning that these will be used in future clinical trials, systematic reviews and clinical practice guidelines. Once established, these could also be used for 'routine follow up' and included in a database. The identified stakeholders are, primarily, women with SUI from various international

backgrounds and additionally healthcare professionals, researchers, and policy makers. Core Outcome Measures in Effectiveness Trials (COMET) guidelines will be adhered to [259]. The protocol was developed with the Standard Protocol Items-Recommendations for Interventional Trials (SPIRIT) checklist. This initiative is supported by Core Outcomes in Women's and Newborn Health (CROWN) which is endorsed by several journals who require authors to report the results for core outcomes within their results rather than alternative non-core outcomes. This should encourage uniform outcome reporting facilitating the possibility of large-scale comparisons and meta-analysis. Once the COS is established, there will be global standardised data which would not only give larger international data sets to analyse but also allow comparisons between countries and seek to understand the differences, which is becoming easier with advances in information technology. Information technology is required to create software solutions to automate outcomes data collection and if electronic records are used to integrate with these.

Regular review

Medical practice can change, and no matter how well designed a database is, changes with new developments or research may require a change to the database, so it is imperative that a future database remains nimble to be easily altered without losing previously gathered data [260].

Database design

The design of the BSUG database is of a surgical database compared to a disease-based database. If it were disease based then the outcomes of conservative measures could be assessed in addition to surgical methods which was the design of the

American Pelvic Floor Disorders Research Registry where conservative management strategies such as pessaries are included [261]. This would follow the whole patient journey from first presentation to the GP, moving to physio, progressing to a surgical procedure and all would have regular long term follow up. This would require a fully national database available to all healthcare professionals involved in continence management. It could also allow information on deferred or avoided operations and which patients are more likely to benefit from physiotherapy.

Funding/support

Adequate governmental support and funding is needed for the BSUG database to be able to be utilised to its full potential.

Benchmarking

The database is currently unable to be used for benchmarking as it is non-mandatory and non-audited. All data is biased towards responders. Regular audit would be needed to ensure all consecutive cases are entered and all complications are entered.

Ultimately, it is likely that the only way to ensure all data is entered, is to make the database mandatory with governmental backing with penalties for non-compliance.

Development of a prognostic tool

An original aim of this thesis was to develop a prediction model. A prediction tool would allow a patient, with SUI, who was considering surgery, to enter personal characteristics and surgical options into the model to generate an individualised likelihood of success, and risk of complications, with each different procedure. This could help with counselling and shared decision making (figure 48) and could be used in conjunction with the NICE decision making tool [235]. It would help establish which intervention may be preferred by patients based upon individual characteristics and acceptance of the risks involved. Some patients may prefer the highest chance of cure of SUI with the knowledge of a higher risk of complications compared to others who would accept lower cure rates to avoid complications [235].

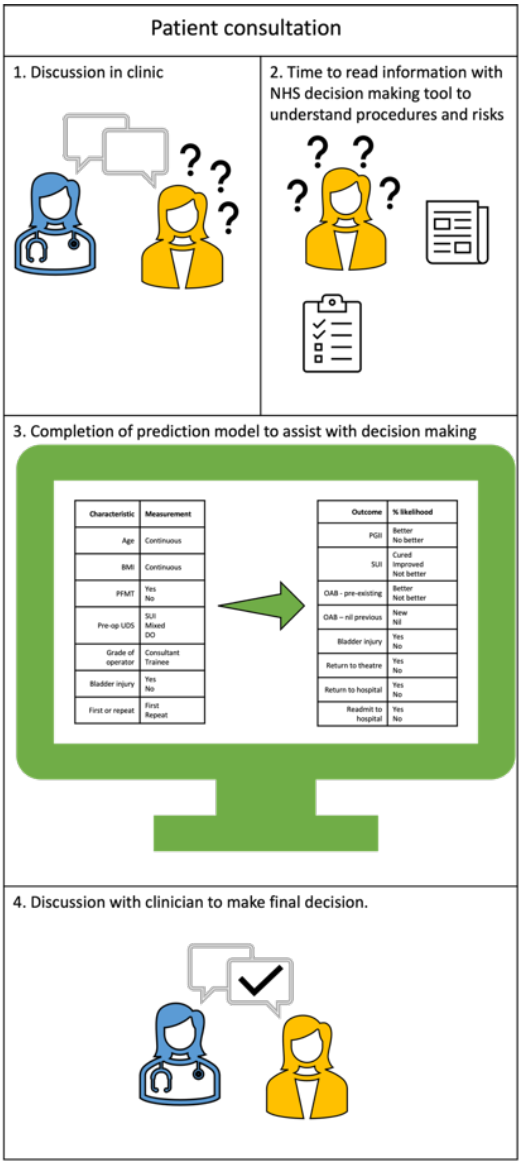


Figure 48: patient consultation to discuss operative choices with prediction model

The BSUG database is a large resource with many procedures stored however there are multiple reasons why it is not suitable to be developed as part of a prediction model.

Development of a prediction model or risk calculator is a complex process with a series of development steps as defined by the PROGRESS group [262]. Potential predictors,

identified by literature review or by data analysis, must be able to be standardised to ensure uniformity when building and ultimately utilising the model. The data used to develop the model should be prospectively collected [262] but if this is not possible, data can be taken from RCTs or from pre-existing datasets. Prospective data collection is preferred as predictive variables in RCTs may not be applicable to clinical practice and pre-existing datasets may not include important predictors. A multivariable analysis of predictors is then performed to identify those predictors that affect the outcome. The model is built using a complex and computationally intensive statistical procedure requiring in-depth knowledge of multiple imputation, modelling, bootstrapping, optimism adjusting, discrimination and calibration. Once the model has been built, its performance must be evaluated by comparing the predicted outcome to the actual outcome using internal and external validation, the latter using a new data set not included in the development of the model. Finally the impact of the model on clinical care and outcomes is assessed such as by an RCT to compare outcomes when the model is used compared to usual care [263].

The development of a prediction model for SUI would be complex. The outcome for the prediction model would have to be chosen and standardised, which as previously described is difficult with multiple outcomes available. The most relevant outcomes for SUI are subjective and therefore affected by the patient so can lead to bias. An objective measure of success for SUI would not align with the commonly accepted aim of treatment which is to improve the quality of life of that patient [8].

Potential predictors for the prediction model that alter outcomes of stress urinary incontinence surgery have been identified from the literature in chapter 1. The standardisation of these predictors poses a challenge to the reproducibility of the data.

Some predictors implicated in altering outcomes of SUI surgery can be standardised such as age, BMI and parity. Other predictors can be categorised such as presence of diabetes, menopausal status and vaginal delivery. Further predictors are harder to standardise such as previous prolapse surgery as the variety for this is so wide so each procedure may need to be entered thus making too many variables for the model. Urodynamic variables such as VLPP, ALPP and MUCP are easy to record in a standardised manner as they are numerical, but there is variation in how UDS are performed thus leading to non-standardisation. An additional difficulty is that surgical techniques are variable with individual clinicians. To standardise technique for RPT and PUB may be possible but for AFS and colposuspension this would be much harder.

Collecting the data prospectively for all predictors of all SUI procedures of interest would require a very large dataset to ensure sufficient numbers. There is not an appropriate RCT that contains all the procedures and all the predictors and there are no existing datasets that would be suitable. For a database to support development of a prediction model it would need to contain all predictors obtained in a standardised manner, surgery would need to be performed in a standardised manner including pre-intra- and post operative processes and there would need to be 100% completion of all fields including long term standardised outcomes.

Ultimately, currently, a prediction model for management of stress urinary incontinence is not possible due to the inability to standardise the predictors, the number of predictors required, the inability to standardise the interventions and the lack of appropriate objective outcome.

Conclusion

This work has been able to demonstrate that RPT dominated SUI surgery until the mesh pause which had significant impact on the types of procedures performed. PUB subsequently rapidly became the most performed procedure with smaller numbers of AFS and colposuspension. Success rates for RPT, AFS and colposuspension were found to be similar with a significantly reduced odds of success for PUB. De novo OAB had significantly decreased odds of developing after PUB compared to RPT. Patients had less post operative complications with PUB, meaning decreased odds of return to theatre, return to hospital and readmission to hospital. Odds of success following RPT were reduced with increased age, BMI, detrusor overactivity in UDS and repeat procedures. Colposuspension outcomes were negatively affected by increased age.

Exploration of the BSUG database identified weaknesses in design, data input and validation and generalizability thus limiting its use in benchmarking and prediction model development.

The BSUG database does not fulfil the criteria for a perfect database but, several significant findings have been discovered which have confirmed the findings of RCTs in real life settings. It is an important resource supporting individual audit and providing real world data for certain questions. It should thus be further developed with input from a wide range of stakeholders to facilitate its wider use in informing clinical practice and as a resource for future research.

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Appendix 1: Research proposal, Funding and Statistician proposal

1. BSUG research grant application
2. BSUG Project Proposal
3. PI agreement from BSUG
4. Confirmation of grant from BSUG
5. Biostatistics support request

British Society of Urogynaecology

BSUG RESEARCH GRANT APPLICATION

I. TITLE PAGE (USE THE TEMPLATE BELOW)			
TITLE OF PROJECT:	Analysis of BSUG database continence procedures. Assessment of ability to use database as a predictive tool. BSUG Database Research: Yes Yes/No		
IS THIS APPLICATION FOR: (MUST SELECT ONE):			
BASIC SCIENCE RESEARCH		**CLINICAL RESEARCH**	YES
DURATION OF RESEARCH STUDY PERIOD:			
From (month/year)	Oct 2018	**To** (month/year)	Oct 2019
PRINCIPLE INVESTIGATOR: (List name and institution, city/country and email address)			
Fiona Bach Birmingham Women's Hospital		fionabach@ yahoo.com	
CO-INVESTIGATORS: List all names with institution, city/country, and email address for each			
Philip Toozs-Hobson Birmingham Women's Hospital		philip.toozs-hobson@ bwnft.nhs.uk	
IS THIS STUDY RECEIVING FUNDING FROM ANOTHER SOURCE:			
Yes		**No**	no
If yes, provide details of the funding (source, amount, duration):			
ETHICS APPROVAL STATUS:			
	Approved (provide approval letter from ethics)		
	Pending (indicate if application submitted and stage of application process)		
x	**Exempt** (provide explanation) See report - individual Caldicott Approval at source		

Covering letter

To Whom It May Concern:

Please find an application for the BSUG funding for work on the BSUG database. It does not follow the format as suggested as it is not set up as a clinical trial so many areas would not be relevant. This will be clear when the proposal is studied.

We are both BSUG members. I am on the database committee who I would hope would be heavily involved in this project if the proposal is successful.

Thank you for considering our proposal

Miss Fiona Bach
Mr Phil Toozs-Hobson

Title:
An analysis of the BSUG database continence procedures to develop a predictive tool

Research questions
A: What are the patients reported outcomes and complications for retropubic tapes, bulking agents, fascial slings and colposuspension recorded on the BSUG database? How do these outcomes and complications vary with different patient characteristics?
B. Can these results from the database be used to generate a predictive tool?

Rational for study
As part of my MD studies, I have analysed the BSUG database to assess patient reported outcomes and complications for retropubic tapes and bulking agents (see attached report and publication list). I have shown the absolute success rates using PGII, change in SUI and OAB symptoms. I have also assessed how these vary depending on different patient characteristics including BMI, urodynamic diagnosis and certain complications. I am in the process of performing logistic regression analysis on the retropubic tapes using the vast number of data included in the database, with statistical support. Once this methodology has been set up using STATA (statistical package) it can be adapted to analyse other procedures from the database, both continence and prolapse, due to the set-up of the excel document that the data is provided in.

We propose to continue the above work to include colposuspension and fascial slings in an identical analysis so a true comparative picture of outcomes for continence surgery can be developed. This is particularly pertinent in view of the current investigation of tapes.

This will ultimately provide clinicians and patients “real life” information on what can be expected from continence surgery. They will be able to assess for themselves the likely outcomes for them dependent on their personal characteristics and the operation they choose.

Aims and objectives
To provide indirect comparisons of outcomes and complications of continence surgeries recorded on the BSUG database (acknowledging no data on decision making)
To assess if changes are required in the database to develop a prognostic model
To develop a prognostic model

Hypothesis
That generating the methodology for predictive modeling of outcome for continence surgery is a. feasible and b. useful using retropubic tape as the initial model (as this has most data)
A prognostic model will require multiple assumptions at present, but development of the model will allow suggestions to be made on how to optimize the database for on going research and improvements in patient care.

Study Methodology
I will continue to work with the statistician to develop the logistic regression analysis for each of the four continence procedures. This will be developed in STATA for retropubic tapes in a way that will ensure it is transferable to the data from the other continence procedures. This process is bespoke and requires considerable statistical support and input to enable the individual data be processed for each of the necessary steps in the methodology.

The prognostic modeling will require considerable statistical time but still with clinical input from ourselves. Prognostic modeling is a very complex and computationally intensive statistical procedure which is why the extensive support is required. The process includes multiple imputation, modeling, bootstrapping, optimism adjusting, discrimination and calibration. Put simply this means the programme uses multiple information to give accurate estimates of risk and then using random samples of the data to test these. The incomplete data in the database means that this process will be even more complex but using multiple imputation can overcome this. Multiple imputation means the computer package creates several possible “imputed” data sets and creates results depending on all these “possible” datasets.

Once the model is set up either it could be applied to prolapse or even to the IUGA database or further validation could be performed using the IUGA database, but this may give different results due to the different international populations.

Ethics
Ethics is not required as each centre is required to have been through the Caldicott guidelines and patients are consented to have their anonymised information included in analysis.

Funding:
Currently the statistician is providing services through the university due to my registration for MD. Through the project I am learning to use STATA so have been preparing the data and running the statistical analysis under guidance. As the statistics becomes more involved and the time requirements increase funding will need to be provided. The statisticians envisage this process would normally require about 6 months fulltime statistical support. We are however have already undertaken much of the work and as such require major support rather than a fulltime person.
We envisage 150 hours @ £60/hr for stats support.
It is impossible at this time to assess how long this will take for the full prognostic model as these are normally developed during clinical trial development so time is required for setting the project up. As the data is already collected this does not need to be done.

Stata courses: Fiona Bach
Introduction to STATA £279
Data Management & Statistical Analysis Using Stata £558
Combined Statistical Modelling & Logistic Regression Using Stata £250

Plan for presentation and distribution of results
We plan to present the model at the BSUG meeting initially and then a paper would be required to present it to the wider community. The prognostic model would be widely available to the membership to improve patient counseling and decisions making.

Future work
This would then lead on to developing a “patient choice model”. We envisage this being an online questionnaire which would allow patients to enter their personal characteristics to give them an idea of the outcomes they might have with each different procedure and whether they could, for example, alter their BMI to allow them the chance of a better outcome.

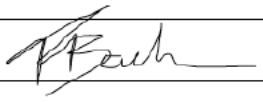
British Society of Urogynaecology

Please read, print and sign the form below. This will need to be uploaded and included with your grant submission.

I. PRINCIPLE INVESTIGATOR'S AGREEMENT

As the principal investigator, I agree that if this research grant proposal is awarded by BSUG, I will submit to the BSUG Research and Development Committee a progress report at 6 months after receipt of initial funding and a final report one month following completion of the research study period.

I also agree to submit the results of this investigation in the form of an abstract(s) to a BSUG Annual Meeting & for any published abstracts or research to be available to view on the BSUG website (subject to copyright)

Name of Principal Investigator:	Fiona Bach
Signature of Principal Investigator:	
Date:	28th August 2018
Name of Department Chair:	Philip Toozs-Hobson
Signature of Department Chair:	P Toozs-Hobson
Date:	31st August 2018

From: Amanda King [redacted]
To: [redacted]
Date: Thursday, 17 January 2019, 01:30 GMT+13

Dear Fiona

Congratulations on your successful application for the BSUG Research Grants 2018/19.

The total grant that will be awarded is £10,000 for your project.

An analysis of the BSUG database continence procedures to develop a predictive tool

Please be advised that the first payment will be made in **January 2019** and the second instalment in **July 2019** – following the successful completing of your **6 month interim report** that will be reviewed by the research Committee.

We will send you the template for completion of the report in due course

We would like to wish you every success with your research project and look forward to receiving the final report.

Please let Amanda King [redacted] have the bank details of where the first payment should be made.

On behalf of Dudley Robinson MD FROG, Chair of the Research Committee, BSUG

Kind regards

Amanda J King

BSUG Secretariat and BSUG Audit Database Administrator
M: +44 7876405822 E: [redacted] W: http://www.bsug.org.uk

Switchboard: +44 20 7772 6200 Registered charity: 1143157
27 Sussex Place, Regent's Park, London NW1 4RG, UK. This email and any attachments to it may be confidential and are intended solely for the use of the individual to whom it is addressed. Unless otherwise stated, any views or opinions expressed are solely those of the author and do not necessarily represent those of the Royal College of Obstetricians and Gynaecologists (RCOG).
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RCOG is a registered charity in England & Wales (No. 213280)

University of Birmingham Institute of Applied Health Research
Biostatistics support request form

PLEASE SUBMIT THIS FORM AT LEAST 12 WEEKS IN ADVANCE OF ANY FUNDING APPLICATION DEADLINE

By requesting support directly from the Biostatistics group, you are agreeing for the information in this form to be held on the Biostatistics support request database:

Note that appropriate intellectual credit for funding (e.g. pink form and co-applicant credit on grants) and when applicable PhD supervisory credit must be given/transferred to the appropriate member of the Biostatistics team. Statistical collaborators should also be co-authors on outputs where appropriate.

Please send the completed form, grant applications/study protocols, to the Biostatistics team by e-mail to:

Section 1: Personal details			
Name:	Fiona Bach	**Position:**	Senior Registrar Birmingham Women's Hospital
Address:	93 Station Road, Harborne. B17 9LR		
Telephone:		**E-mail:**	

Please add any other IAHR staff and key investigators in the 'Comments' section below.

Section 2: Current stage and funding position						
a) Current stage of the project: *Mark appropriate box with an X*	Idea/Protocol Stage		Analysis/write-up	**x**		
	Other: please specify:					
b) Current funding *Mark appropriate box with an X*	Idea/ Funding Application in draft		Submitted for Funding		Funded	x
	Unfunded Research (please explain why there is no funding)					
c) Have you contacted the Research Design Service or a clinical trials unit? If so who and when?	No					
d) If funded: how much money is available for	Up to £7000 (possibly more – up to £9000) This would be split up to £3000 initially then further funding is released based on the initial outputs.					

statistical support?	
e) Name of Funder/scheme or proposed funder(s)/ scheme(s):	BSUG – British Society of Urogynaecology
f) Deadline for funding application?	Accepted

Section 3: Request type						
a) Where are you based?	IAHR		MDS		Other	University of Birmingham
b) Are you?	Staff		PHD student		Other student	On 2 year MD - Institute of Metabolism and Systems Research (IMSR), University of Birmingham
	Other – Please specify					

c) Type of support requested from the biostatistics team. *Mark appropriate boxes with an X*	Help designing the study	
	Help writing the funding application	
	Data Management and Data cleaning advice	X
	Oversight of statistical analysis	X
	Undertaking of statistical analysis	X
	Help paper writing	
	Other: Please specify: **see attached information**	
d) Have you already discussed this with anyone in the Biostatistics group? If so who?	I was initially working with Alice Sitch who was very kindly helping me out however now the project has become a lot more involved and the funding has meant it is a much bigger project.	
e) Timeline for expected work and amount involved.	First £3000 available now with £4000 to be released after 6 months depending on the outputs.	

Section 4: Project summary Please provide a brief description of your proposed study. When submitting this form, please also provide any other study related documents e.g. a draft grant application or draft protocol if available.	
a) Project Title:	An analysis of the BSUG database continence procedures to develop a predictive tool

b) Research Question:	A: What are the patients reported outcomes and complications for retropubic tapes, bulking agents, fascial slings and colposuspension recorded on the BSUG database? How do these outcomes and complications vary with different patient characteristics? B. Can these results from the database be used to generate a predictive tool?						
c) Disease Area:	Urogynaecology						
d) Type of question *Mark appropriate box(es) with an X*	Intervention		Diagnosis		Aetiology		
	Prognosis	x		Descriptive e.g. prevalence			
	Other – Please specify						
e) Is the project an evidence synthesis?							
f) Type(s) of data: *Mark appropriate box with an X*	Trial		Observational		Routine		
	Other – please specify:						
g) Methodological approach: **AND** **h) Rationale:**	**Background** The British Society of Urogynaecology (BSUG) database is a surgical database that currently has over 140,000 surgical entries. I have been given access to the data for the stress incontinence procedures which includes over 20,000 patients. The database records pre-operative patient characteristics such as age, weight, urodynamic diagnosis and BMI then records the operation and intraoperative complications. The patient reported outcome and later complications are then recorded at the follow up appointment. There are 4 potential operations that would be suitable for most patients with stress incontinence each with a range of complications, adverse effects and variable success rates meaning it is difficult for patients to decide which operation is right for them. **Aims and objectives** To provide indirect comparisons of outcomes and complications of continence surgeries recorded on the BSUG database (acknowledging no data on decision making) To assess if changes are required in the database to develop a prognostic model To assess the feasibility of developing a prognostic model						

	Hypothesis That generating the methodology for predictive modeling of outcome for continence surgery is a. feasible and b. useful using retropubic tape as the initial model (as this has most data) A prognostic model will require multiple assumptions at present, but development of the model will allow suggestions to be made on how to optimize the database for ongoing research and improvements in patient care. **Study Methodology** I have published 2 papers (attached) and have a third in the editing stage. I have developed the logistic regression analysis in STATA for two of the continence procedures. The prognostic modelling is far beyond my statistical knowledge, but I would still like to be aware of the process. I understand prognostic modelling to be a very complex and computationally intensive statistical procedure which is why the extensive support is required. There is incomplete data in the database so this means that the process will be even more complex and part of the project will be to identify whether this modelling will be possible ?using multiple imputation to overcome this. Once the model is set up either it could be applied to prolapse or even to the IUGA database or further validation could be performed using the IUGA database but this may give different results due to the different international populations.
i) Expected outputs:	We plan to present the model at the BSUG meeting initially and then a paper would be required to present it to the wider community. The prognostic model would be widely available to the membership to improve patient counseling and decisions making. **Future work** This would then lead on to developing a “patient choice model”. We envisage this being an online questionnaire which would allow patients to enter their personal characteristics to give them an idea of the outcomes they might have with each different procedure and whether they could, for example, alter their BMI to allow them the chance of a better outcome.

j) Is a protocol outline available	na

Section 5: Any other information	
a) Other Comments: Please give details of any other IAHR staff and key investigators	See attached papers on email.

Appendix 2: Patient consent form to allow data to be added to the BSUG database

British Society of Urogynaecology
Registered charity No 1143157

Please attach patient sticker here or record:
Name:……
Unit No:

NHS No: ……
D.O.B: ……/……/……
Gender: Female Cons: ……

THE BRITISH SOCIETY OF UROGYNAECOLOGY (BSUG) DATABASE – PATIENT CONSENT FORM

Dear Patient,

The British Society of Urogynaecology ("BSUG") is a National group of gynaecologists with a special interest and expertise in the treatment of incontinence and prolapse. BSUG is a Registered Charity (Number – 1143157).

BSUG has developed a Database of clinical and surgical information which we hope will make procedures as safe and effective as possible. Hospital Trusts and individual Consultants can use this information to look at their practice and make any necessary changes to improve patient care.

The patient information held in the BSUG database comprises: Name, Hospital Number and Date of Birth ("Patient Identifiable Data") together with clinical and surgical information. The "Patient Identifiable Data" is held securely on the NHS computer network (N3) and can only be accessed by your consultant. The information on the BSUG database is recorded in line with the General Data Protection Regulation (GDPR) (2018).

If you agree to allow us to enter your Patient Identifiable Data into the BSUG database this will signify your consent to the following:

1. The processing of my Patient Identifiable Data and clinical information by BSUG for research and auditing purposes as outlined above.

2. The disclosure by BSUG of my Patient Identifiable Data and clinical information to its information technology service providers (ICE ICT), where such suppliers have agreed to adopt appropriate technical and organisation measures to protect the security of my Patient Identifiable Data and only to process it in accordance with BSUG's instructions.

Please note that you can request access to view your entry on the BSUG database from your consultant team and can request that this is deleted at any time by sending a written notice to your consultant OR to the following address:

BSUG c/o BSUG, Registered charity no: 1143157, Royal College of Obstetricians & Gynaecologists 27 Sussex Place Regents Park London NW1 4RG.

Please indicate that you have read and understood this consent form relating to the BSUG database and agree to have your case added by signing below:

Signed…… Date……/……/…….

Print Name……

Name of person obtaining consent: ……

Please ask if you would like a copy of this consent form.

Appendix 3: Primary pilot analysis STATA do.file, for chapter 2

This is the 'Do file' the author created for the calculations. It has explanations of how the processes were achieved so they can be reapplied in future.

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Section 1: Initial set up and preparing the dataset

```
* Copy the excel spreadsheet into STATA
*******
* It has to be altered first for the column headings - most are ok but the following
have to be changed

* Pre-Op-QOL-UI       Pre-Op-QOL-VS  Pre-Op-QOL-SM  Pre-Op-QOL-LUTS       Pre-Op-QOL-
OAB
*Pre-Op-QOL-Other
* Intra-op-Graft Complication YN     Intra-op-Graft Complication GCC
*Intra-op-Ureteric injury Intra-op-Bladder injury Intra-op-VaginalButton-holing
*Intra-op-Urethral injury     Intra-op-Bowel injury  Intra-op-Vascular injury
*Intra-op-Neurological injury Intra-op-Blood loss > 500ml
* RTT Return to theatre for procedure-related event within 72 hrs
*RTTActivebleeding RTT Drainage of haematoma RTT Bowel injury RTT Bladderinjury
*RTT Ureteric injury  RTT Voiding difficulty RTT Other
* RTH Return to hospital within 30 days for procedure related event
*RTH Trial without catheter (TWOC     RTH Voiding difficulty RTH Constipation
*RTH Infection RTH Active bleeding    RTH Haematoma  RTH Bowel injury
*RTH Bladder injury    RTH Ureteric injury    RTH Other
* RdTH Readmitted to hospital within 30 days for procedure related event
*RdTH Trial without catheter (TWOC    RdTH Voiding difficulty       RdTH Constipation
*RdTH Infection       RdTH Active bleeding   RdTH Haematoma RdTH Bowel injury
*RdTH Bladder injury  RdTH Ureteric injury   RdTH Other
* Post-Op-QOL-UI       Post-Op-QOL-VS Post-Op-QOL-SM Post-Op-QOL-LUTS
*Post-Op-QOL-OAB      Post-Op-QOL-Other
* F/u Does patient require catheters  F/u If Yes, were they required pre-op
*F/u Post-op Graft Complication YN    F/u Post-op Graft Complication GCC
* Long term F/u Time from surgery (months)
*Long term F/u Same site recurrent prolapse requiring conservative therapy
*Long term F/u Same site recurrent prolapse requiring surgery
*Long term F/u New site prolapse
*Long term F/u Recurrent incontinence treated conservatively
*Long term F/u Recurrent incontinence requiring surgery
*Long term F/u New incontinence treated conservatively
*Long term F/u New incontinence requiring surgery
*Long term F/u Voiding difficulty     Long term F/u New onset constipation
*Long term F/u Obstructive defaecation       Long term F/u De novo dyspareunia
*Long term F/u Vaginal narrowing secondary to mesh retraction
*Long term F/u Mesh erosion   Long term F/u Pelvic   Long term F/u Vaginal
*Long term F/u Bladder Long term F/u Urethral
*Long term F/u Graft Complication YN  Long term F/u Graft Complication GCC
* ePAQ Urinary
* ePAQ Bowel
* ePAQ Vaginal
* ePaq Sexual
* F/u 1
* F/u 2
* F/u 3

*******
import excel "name of spreadsheet here", sheet("bsug_spreadsheet_2016-01-27") firstrow
clear
*******

* When some column titles come across they become shortened to the same as
* previous one so they just get called the letter names - need to change them
* Some of the column titles don't make so much sense - need to change them

rename Catheterisationrequiredformor CatheterisationMoreThan10days
rename FailedtrialwithoutcatheterT FailedTWOC
rename Indwellingcatheterafterbladde IndwellingCathAfterBladdeInjury
rename Other Cath10daysOther
rename RdTHReadmittedtohospitalwith RdTHReadmittedtohospital30dy
rename RTHTrialwithoutcatheterTWOC RTHTWOC
rename RdTHTrialwithoutcatheterTWO RdTHTWOC
rename CU GIIProlapse
rename GlobalImpressionofImprovement GIIIncontinence
rename LongtermFuSamesiterecurren LongtermFuSamesiterecProCon
rename DZ LongtermFuSamesiterecProSur
rename LongtermFuRecurrentincontin LongtermFuRecurrentInconCon
rename EC LongtermFuRecurrentInconSur
rename LongtermFuNewincontinencet LongtermFuNewIncontCon
rename LongtermFuNewincontinencer LongtermFuNewIncontSur
```

```
rename FuIfYesweretheyrequiredp FuIfYesWereTheyReqPreOp
rename FuPostopGraftComplicationY FuPostopGraftCompYN
rename FuPostopGraftComplicationG FuPostopGraftCompGCC
rename LongtermFuVaginalnarrowing LongtermFuVagNarrowMESH
rename LongtermFuGraftComplication LongtermFuGraftCompYN
rename EQ LongtermFuGraftComplGCC
rename ePAQUrinaryOveractiveBladder ePAQUrinaryOABpre
rename EW ePAQUrinaryOABpost
rename ePAQUrinaryStressUrinaryInco ePAQUrinarySUIpre
rename EY ePAQUrinarySUIpost
rename Fu1Whatisthefollowupinte Fu1Whatisfollowupinterval
rename Fu1GlobalImpressionofImpro Fu1GIIIncontinence
rename GH Fu1GIIProlapse
rename Fu1PostopGraftComplication Fu1PostopGraftCompYN
rename HF Fu1PostopGraftCompGCC
rename Fu2GlobalImpressionofImpro Fu2GIIIncontinence
rename HM Fu2GIIProlapse
rename Fu2PostopGraftComplication Fu2PostopGraftCompYN
rename IK Fu2PostopGraftCompGCC
rename Fu3GlobalImpressionofImpro Fu3GIIIncontinence
rename IR Fu3GIIProlapse

**Can recode things later to make them easier to write up**

******* Now it's all set up.
*****************************************************
*This is useful as a template for all things
*tab **var**
*
*encode **var**, generate (**var**num)
*label list **var**num
*
*recode  **var**num ""unanswered""=.
*
*tab **var**num
*
*SO to make it easy to copy and paste it is this.......
*
*
*tab
*
*encode , generate (num)
*label list num
*
*recode  num =.
*
*tab num
*****************************************************

*************************************************************************
*************************************************************************
```

Section 2: Age

```
* Summary about age

summ Ageatop

    Variable |        Obs        Mean    Std. Dev.       Min        Max
-------------+---------------------------------------------------------
     Ageatop |     18,763    51.76528    49.68222      -1960       2011

*Remove ages <18 and >100

replace Ageatop = . if Ageatop > 100 | Ageatop < 18
(534 real changes made, 534 to missing)

*Summary after removing <18 and >100

. summ Ageatop

    Variable |        Obs        Mean    Std. Dev.       Min        Max
-------------+---------------------------------------------------------
     Ageatop |     18,229    52.28855    11.74235         18        100

*Do a graph of ages
histogram Ageatop, width(1)


**For groups of age
*To look at the groups of age - I made a new variable called "Agegrouped" by copying "Ageatop" and then
removed those aged under 18, and created groups of 18-<50, 50-<75 and 75-100 and then labelled them as
such

clonevar Agegrouped = Ageatop
(534 missing values generated)

recode Agegrouped 0/17.9999999=. 18/49.999999999=1 50/75=2 75/100=3
Agegrouped: 18229 changes made

tab Agegrouped
  Age at op |      Freq.     Percent        Cum.
------------+-----------------------------------
          1 |      9,339       51.24       51.24
          2 |      8,159       44.76       96.00
          3 |        729        4.00      100.00
------------+-----------------------------------
      Total |     18,227      100.00

label define Agegrouped 1 "18-<50" 2 "50-<75" 3 "75-100", modify
label values Agegrouped Agegrouped

tab Agegrouped

  Age at op |      Freq.     Percent        Cum.
------------+-----------------------------------
     18-<50 |      9,339       51.24       51.24
     50-<75 |      8,159       44.76       96.00
     75-100 |        729        4.00      100.00
------------+-----------------------------------
      Total |     18,227      100.00
```

Section 3: Pelvic Floor exercises

```
encode Pelvicfloorexercisesoffered, generate (Pelvicfloorexercisesofferednum)
label list Pelvicfloorexercisesofferednum
Pelvicfloorexercisesofferednum:
           1  Unanswered
           2 No
           3 Yes - accepted
           4 Yes - declined

tabulate Pelvicfloorexercisesofferednum

  Pelvic floor |
     exercises |
       offered |      Freq.     Percent        Cum.
---------------+-----------------------------------
    Unanswered |      2,253       12.01       12.01
            No |      1,425        7.59       19.60
Yes - accepted |     14,535       77.47       97.07
Yes - declined |        550        2.93      100.00
---------------+-----------------------------------
         Total |     18,763      100.00

*Then I removed those that were "unanswered"

recode  Pelvicfloorexercisesofferednum 1=.
(Pelvicfloorexercisesofferednum: 2253 changes made)

tab Pelvicfloorexercisesofferednum
  Pelvic floor |
     exercises |
       offered |      Freq.     Percent        Cum.
---------------+-----------------------------------
            No |      1,425        8.63        8.63
Yes - accepted |     14,535       88.04       96.67
Yes - declined |        550        3.33      100.00
---------------+-----------------------------------
         Total |     16,510      100.00

*Then make it into binary for the Chi² test

generate PelvicfloorexerciseforChi = 0 if Pelvicfloorexercisesofferednum ==3
(4,228 missing values generated)
replace PelvicfloorexerciseforChi = 1 if Pelvicfloorexercisesofferednum
==2|Pelvicfloorexercisesofferednum ==4
(1,975 real changes made)
*0 = had PFE      1 = Did not have PFE     (2253 unanswered)

tab PelvicfloorexerciseforChi

 Pelvicfloor |
exercisefor |
        Chi |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |     14,535       88.04       88.04
          1 |      1,975       11.96      100.00
------------+-----------------------------------
      Total |     16,510      100.00

*******************************************************************************
**Who Supervised the exercises?

encode Whosupervisedtheexercises, generate (Whosupervisedtheexercisesnum)
label list Whosupervisedtheexercisesnum
Whosupervisedtheexercisesnum:
           1  Unanswered
           2 Continence advisor
           3 Declined PFE
           4 GP
           5 Nurse specialist
           6 Physiotherapist
           7 Self-examination

tabulate Whosupervisedtheexercisesnum
```

Who supervised the exercises	Freq.	Percent	Cum.
Unanswered	4,239	22.59	22.59
Continence advisor	2,365	12.60	35.20
Declined PFE	301	1.60	36.80
GP	116	0.62	37.42
Nurse specialist	733	3.91	41.33
Physiotherapist	10,144	54.06	95.39
Self-examination	865	4.61	100.00
Total	18,763	100.00	

```
recode Whosupervisedtheexercisesnum    1=.
(Whosupervisedtheexercisesnum: 4239 changes made)

tab Whosupervisedtheexercisesnum
```

Who supervised the exercises	Freq.	Percent	Cum.
Continence advisor	2,365	16.28	16.28
Declined PFE	301	2.07	18.36
GP	116	0.80	19.15
Nurse specialist	733	5.05	24.20
Physiotherapist	10,144	69.84	94.04
Self-examination	865	5.96	100.00
Total	14,524	100.00	

Section 4: Pre Op Urodynamics

```
encode Preopurodynamicsperformed, generate (Preopurodynamicsperformednum)
label list Preopurodynamicsperformednum
Preopurodynamicsperformednum:
           1  Unanswered
           2 No
           3 Yes

tabulate Preopurodynamicsperformednum
     Pre-op |
urodynamics |
  performed |      Freq.     Percent        Cum.
------------+-----------------------------------
 Unanswered |      1,058        5.64        5.64
         No |        601        3.20        8.84
        Yes |     17,104       91.16      100.00
------------+-----------------------------------
      Total |     18,763      100.00


recode Preopurodynamicsperformednum 1=.
(Preopurodynamicsperformednum: 1058 changes made)

tab Preopurodynamicsperformednum
     Pre-op |
urodynamics |
  performed |      Freq.     Percent        Cum.
------------+-----------------------------------
         No |        601        3.39        3.39
        Yes |     17,104       96.61      100.00
------------+-----------------------------------
      Total |     17,705      100.00

*******************************************************************************
**Pre Op UDS Diagnosis

*this is for the descriptive stats
encode PreopUrodynamicdiagnosis, generate (PreOpUDSDes)
label list PreOpUDSDes
           1 DOA
           2 DOA,Mixed USI+DOA,USI
           3 DOA,Mixed USI+DOA,USI,Voiding dysfunction
           4 DOA,Normal
           5 DOA,Occult USI
           6 DOA,Overflow/chronic retention,USI
           7 DOA,USI
           8 DOA,USI,Voiding dysfunction
           9 DOA,Voiding dysfunction
          10 Fistula (vesico-vaginal)
          11 Mixed USI+DOA
          12 Mixed USI+DOA,Normal
          13 Mixed USI+DOA,Overflow/chronic retention
          14 Mixed USI+DOA,USI
          15 Mixed USI+DOA,Unanswered
          16 Mixed USI+DOA,Voiding dysfunction
          17 Normal
          18 Normal,USI
          19 Normal,Voiding dysfunction
          20 Occult USI
          21 Occult USI,USI
          22 Occult USI,Voiding dysfunction
          23 Overflow/chronic retention
          24 Overflow/chronic retention,USI
          25 USI
          26 USI,Unanswered
          27 USI,Voiding dysfunction
          28 USI>USI/option><option value=
          29 Unanswered
          30 Unanswered>Unanswered/option><option value=
          31 Voiding dysfunction

tab PreOpUDSDes
```

Pre-op Urodynamic diagnosis	Freq.	Percent	Cum.
DOA	73	0.43	0.43
DOA,Mixed USI+DOA,USI	1	0.01	0.43
DOA,Mixed USI+DOA,USI,Voiding dysfuncti	1	0.01	0.44
DOA,Normal	1	0.01	0.45
DOA,Occult USI	2	0.01	0.46
DOA,Overflow/chronic retention,USI	1	0.01	0.46
DOA,USI	38	0.22	0.69
DOA,USI,Voiding dysfunction	4	0.02	0.71
DOA,Voiding dysfunction	6	0.04	0.74
Fistula (vesico-vaginal)	1	0.01	0.75
Mixed USI+DOA	2,616	15.32	16.07
Mixed USI+DOA,Normal	1	0.01	16.07
Mixed USI+DOA,Overflow/chronic retentio	3	0.02	16.09
Mixed USI+DOA,USI	10	0.06	16.15
Mixed USI+DOA,Unanswered	1	0.01	16.16
Mixed USI+DOA,Voiding dysfunction	103	0.60	16.76
Normal	471	2.76	19.52
Normal,USI	23	0.13	19.65
Normal,Voiding dysfunction	4	0.02	19.68
Occult USI	115	0.67	20.35
Occult USI,USI	2	0.01	20.36
Occult USI,Voiding dysfunction	8	0.05	20.41
Overflow/chronic retention	1	0.01	20.41
Overflow/chronic retention,USI	8	0.05	20.46
USI	13,048	76.41	96.87
USI,Unanswered	6	0.04	96.90
USI,Voiding dysfunction	429	2.51	99.41
USI>USI/option><option value=	1	0.01	99.42
Unanswered	95	0.56	99.98
Unanswered>Unanswered/option><option va	1	0.01	99.98
Voiding dysfunction	3	0.02	100.00
Total	17,077	100.00	

```
*re-group them to be the same as the previous paper

*recode to include 1 is USI, 2 is USI+voidingdysfunction, 3 is Normal, 4 is Mixed, 5
is Mixed+voiding dysfunction, 6 is DOA, 7 is normal, 8 is voiding dysfunction
recode PreOpUDSDes 1=6 2=4 3=5 4=6 5=4 6=5 7=4 8=5 9=6 10=. 11=4 12=4 13=5 14=4 15=4
16=5 17=7 18 = 1 19 = 8 20 = 1 21=1 22=2 23=8 24=2 25=1 26=1 27=2 28=1 29=. 30=. 31=8

(PreOpUDSDes: 17077 changes made)


*rename them!
label define PreOpUDSDes 1 "USI", modify
label define PreOpUDSDes 2 "USI and voiding dysfunction", modify
label define PreOpUDSDes 3 "Normal", modify
label define PreOpUDSDes 4 "Mixed", modify
label define PreOpUDSDes 5 "Mixed and voiding dysfunction", modify
label define PreOpUDSDes 6 "DOA", modify
label define PreOpUDSDes 7 "Normal", modify
label define PreOpUDSDes 8 "Voiding dysfunction", modify


tab PreOpUDSDes
```

Pre-op Urodynamic diagnosis	Freq.	Percent	Cum.
USI	13,195	77.71	77.71
USI+voiding dysfunction	445	2.62	80.33
Mixed	2,669	15.72	96.05
Mixed+voiding dysfunction	112	0.66	96.71
DOA	80	0.47	97.18
Normal	471	2.77	99.95
voiding dysfunction	8	0.05	100.00
Total	16,980	100.00	

```
generate onlyUDSUSI = 1 if PreOpUDSDes == 1
(5,568 missing values generated)

**SEE LATER FOR THE TABLE OF PGIIII BY UDS
```

```
*this is for the Chi test and log regression
encode PreopUrodynamicdiagnosis, generate (PreOpUDSChi)
label list PreOpUDSChi
           1 DOA
           2 DOA,Mixed USI+DOA,USI
           3 DOA,Mixed USI+DOA,USI,Voiding dysfunction
           4 DOA,Normal
           5 DOA,Occult USI
           6 DOA,Overflow/chronic retention,USI
           7 DOA,USI
           8 DOA,USI,Voiding dysfunction
           9 DOA,Voiding dysfunction
          10 Fistula (vesico-vaginal)
          11 Mixed USI+DOA
          12 Mixed USI+DOA,Normal
          13 Mixed USI+DOA,Overflow/chronic retention
          14 Mixed USI+DOA,USI
          15 Mixed USI+DOA,Unanswered
          16 Mixed USI+DOA,Voiding dysfunction
          17 Normal
          18 Normal,USI
          19 Normal,Voiding dysfunction
          20 Occult USI
          21 Occult USI,USI
          22 Occult USI,Voiding dysfunction
          23 Overflow/chronic retention
          24 Overflow/chronic retention,USI
          25 USI
          26 USI,Unanswered
          27 USI,Voiding dysfunction
          28 USI>USI/option><option value=
          29 Unanswered
          30 Unanswered>Unanswered/option><option value=
          31 Voiding dysfunction

tab PreOpUDSChi

            Pre-op Urodynamic diagnosis |      Freq.     Percent        Cum.
----------------------------------------+-----------------------------------
                                    DOA |         73        0.43        0.43
                   DOA,Mixed USI+DOA,USI |          1        0.01        0.43
DOA,Mixed USI+DOA,USI,Voiding dysfuncti |          1        0.01        0.44
                             DOA,Normal |          1        0.01        0.45
                          DOA,Occult USI |          2        0.01        0.46
     DOA,Overflow/chronic retention,USI |          1        0.01        0.46
                                DOA,USI |         38        0.22        0.69
            DOA,USI,Voiding dysfunction |          4        0.02        0.71
                DOA,Voiding dysfunction |          6        0.04        0.74
               Fistula (vesico-vaginal) |          1        0.01        0.75
                           Mixed USI+DOA |      2,616       15.32       16.07
                  Mixed USI+DOA,Normal |          1        0.01       16.07
Mixed USI+DOA,Overflow/chronic retentio |          3        0.02       16.09
                       Mixed USI+DOA,USI |         10        0.06       16.15
              Mixed USI+DOA,Unanswered |          1        0.01       16.16
      Mixed USI+DOA,Voiding dysfunction |        103        0.60       16.76
                                 Normal |        471        2.76       19.52
                              Normal,USI |         23        0.13       19.65
             Normal,Voiding dysfunction |          4        0.02       19.68
                              Occult USI |        115        0.67       20.35
                         Occult USI,USI |          2        0.01       20.36
         Occult USI,Voiding dysfunction |          8        0.05       20.41
             Overflow/chronic retention |          1        0.01       20.41
         Overflow/chronic retention,USI |          8        0.05       20.46
                                    USI |     13,048       76.41       96.87
                         USI,Unanswered |          6        0.04       96.90
                 USI,Voiding dysfunction |        429        2.51       99.41
          USI>USI/option><option value= |          1        0.01       99.42
                              Unanswered |         95        0.56       99.98
Unanswered>Unanswered/option><option va |          1        0.01       99.98
                    Voiding dysfunction |          3        0.02      100.00
----------------------------------------+-----------------------------------
                                  Total |     17,077      100.00


**group them together
*recode it so 1 is USI, 2 is USI+vd, 3 is any DO
```

```
recode PreOpUDSChi 1=3 2=3 3=3 4=3 5=3 6=3 7=3 8=3 9=3 10=. 11=3 12=3 13=3 14=3 15=3
16=3 17=. 18=1 19=. 20=1 21=1 22=2 23=. 24=1 25=1 26=1 27=2 28=1 29=. 30=. 31=.
(PreOpUDSChi: 17076 changes made) - it is not 17077 because it just happens that
3=3.....

(576 - missing values created - I calculated this from above table - 16501 + 576 =
17077 so this is correct)

*rename them
label define PreOpUDSChi 1 "USI", modify
label define PreOpUDSChi 2 "USI+vd", modify
label define PreOpUDSChi 3 "AnyDO", modify

tab PreOpUDSChi

            Pre-op Urodynamic diagnosis |      Freq.     Percent        Cum.
----------------------------------------+-----------------------------------
                                    USI |     13,203       80.01       80.01
                                USI+vd |        437        2.65       82.66
                                 AnyDO |      2,861       17.34      100.00
----------------------------------------+-----------------------------------
                                  Total |     16,501      100.00
*(I have checked this table against the original figure and it is correct)


**This is to calculate the catheter rates for voiding dysfunction vs no voiding
dysfunciton as a Chi squared
 encode PreopUrodynamicdiagnosis, generate (PreOpUDSCathChi)

 label list PreOpUDSCathChi
PreOpUDSCathChi:
           1 DOA
           2 DOA,Mixed USI+DOA,USI
           3 DOA,Mixed USI+DOA,USI,Voiding dysfunction
           4 DOA,Normal
           5 DOA,Occult USI
           6 DOA,Overflow/chronic retention,USI
           7 DOA,USI
           8 DOA,USI,Voiding dysfunction
           9 DOA,Voiding dysfunction
          10 Fistula (vesico-vaginal)
          11 Mixed USI+DOA
          12 Mixed USI+DOA,Normal
          13 Mixed USI+DOA,Overflow/chronic retention
          14 Mixed USI+DOA,USI
          15 Mixed USI+DOA,Unanswered
          16 Mixed USI+DOA,Voiding dysfunction
          17 Normal
          18 Normal,USI
          19 Normal,Voiding dysfunction
          20 Occult USI
          21 Occult USI,USI
          22 Occult USI,Voiding dysfunction
          23 Overflow/chronic retention
          24 Overflow/chronic retention,USI
          25 USI
          26 USI,Unanswered
          27 USI,Voiding dysfunction
          28 USI>USI/option><option value=
          29 Unanswered
          30 Unanswered>Unanswered/option><option value=
          31 Voiding dysfunction

tab PreOpUDSCathChi

            Pre-op Urodynamic diagnosis |      Freq.     Percent        Cum.
----------------------------------------+-----------------------------------
                                    DOA |         73        0.43        0.43
                   DOA,Mixed USI+DOA,USI |          1        0.01        0.43
DOA,Mixed USI+DOA,USI,Voiding dysfuncti |          1        0.01        0.44
                              DOA,Normal |          1        0.01        0.45
                          DOA,Occult USI |          2        0.01        0.46
     DOA,Overflow/chronic retention,USI |          1        0.01        0.46
                                DOA,USI |         38        0.22        0.69
            DOA,USI,Voiding dysfunction |          4        0.02        0.71
                DOA,Voiding dysfunction |          6        0.04        0.74
               Fistula (vesico-vaginal) |          1        0.01        0.75
```

```
                           Mixed USI+DOA |      2,616       15.32       16.07
                     Mixed USI+DOA,Normal |          1        0.01       16.07
Mixed USI+DOA,Overflow/chronic retentio |          3        0.02       16.09
                       Mixed USI+DOA,USI |         10        0.06       16.15
                 Mixed USI+DOA,Unanswered |          1        0.01       16.16
       Mixed USI+DOA,Voiding dysfunction |        103        0.60       16.76
                                  Normal |        471        2.76       19.52
                               Normal,USI |         23        0.13       19.65
             Normal,Voiding dysfunction |          4        0.02       19.68
                               Occult USI |        115        0.67       20.35
                          Occult USI,USI |          2        0.01       20.36
          Occult USI,Voiding dysfunction |          8        0.05       20.41
              Overflow/chronic retention |          1        0.01       20.41
          Overflow/chronic retention,USI |          8        0.05       20.46
                                     USI |     13,048       76.41       96.87
                               USI,Unanswered |          6        0.04       96.90
                    USI,Voiding dysfunction |        429        2.51       99.41
           USI>USI/option><option value= |          1        0.01       99.42
                               Unanswered |         95        0.56       99.98
Unanswered>Unanswered/option><option va |          1        0.01       99.98
                     Voiding dysfunction |          3        0.02      100.00
-----------------------------------------+-----------------------------------
                                   Total |     17,077      100.00
```

```
*Group them into 0 = voiding difficulties vs 1 = no voiding difficulties
recode PreOpUDSCathChi 1=1 2=1 3=0 4=1 5=1 6=0 7=1 8=0 9=0 10=. 11=1 12=1 13=0 14=1
15=1 16=0 17=1 18=1 19=0 20=1 21=1 22=0 23=0 24=0 25=1 26=1 27=0 28=1 29=. 30=. 31=0
 (PreOpUDSCathChi: 17004 changes made)

 *rename them!
label define PreOpUDSCathChi 0 "Voiding difficulties", modify
label define PreOpUDSCathChi 1 "No voiding difficulties", modify

tab PreOpUDSCathChi
```

```
            Pre-op Urodynamic diagnosis |      Freq.     Percent        Cum.
----------------------------------------+-----------------------------------
                  Voiding difficulties |        571        3.36        3.36
               No voiding difficulties |     16,409       96.64      100.00
----------------------------------------+-----------------------------------
                                  Total |     16,980      100.00
```

Section 5: BMI

```
**Height and Weight are ok

*Find out about what BMI looks like

summ BMI
    Variable |        Obs        Mean    Std. Dev.       Min        Max
-------------+---------------------------------------------------------
         BMI |     18,763    18.54781    25.89034          0       2900

clonevar BMIcorrect = BMI
**this is all the BMI without exclusions


*get rid of BMI <15 and >65
replace BMIcorrect = . if BMIcorrect > 65 | BMIcorrect < 15
 (6,918 real changes made, 6,918 to missing)

. summ BMIcorrect


    Variable |        Obs        Mean    Std. Dev.       Min        Max
-------------+---------------------------------------------------------
  BMIcorrect |     11,859    28.93667    5.448568         15   60.56865


*Do a graph of BMI

histogram BMIcorrect, width(1)

clonevar BMIgrouped = BMI

recode BMIgrouped 0/15=. 15/17.9999999=1 18/24.999999999=2 25/29.999999999=3
30/34.999999999999=4 35/39.9999999999=5 40/44.999999999999=6 45/49.9999999999999=7
50/65=8 65/1000000000=.
* BMIgrouped: 18763 changes made

tab BMIgrouped

        BMI |      Freq.     Percent        Cum.
------------+-----------------------------------
          1 |         13        0.11        0.11
          2 |      2,943       24.82       24.93
          3 |      4,401       37.11       62.04
          4 |      2,838       23.93       85.98
          5 |      1,209       10.20       96.17
          6 |        338        2.85       99.02
          7 |         92        0.78       99.80
          8 |         24        0.20      100.00
------------+-----------------------------------
      Total |     11,858      100.00

label define BMIgrouped 1 "15-<18" 2 "18-<25" 3 "25-<30" 4 "30-<35" 5 "35-<40" 6 "40-
<45" 7 "45-<50" 8 "50-<65", modify
label values BMIgrouped BMIgrouped

**label define labname 0 "group1" 1 "group 2"
**label values varname labname

 tab BMIgrouped

        BMI |      Freq.     Percent        Cum.
------------+-----------------------------------
     15-<18 |         13        0.11        0.11
     18-<25 |      2,943       24.82       24.93
     25-<30 |      4,401       37.11       62.04
     30-<35 |      2,838       23.93       85.98
     35-<40 |      1,209       10.20       96.17
     40-<45 |        338        2.85       99.02
     45-<50 |         92        0.78       99.80
     50-<65 |         24        0.20      100.00
------------+-----------------------------------
      Total |     11,858      100.00
```

Section 6: Anaesthetic

```
tab Anaestheticused

  Anaesthetic |
          used |      Freq.     Percent        Cum.
---------------+-----------------------------------
   Unanswered |        325        1.73        1.73
       Caudal |          5        0.03        1.76
           GA |     12,945       68.99       70.75
  GA + Caudal |        343        1.83       72.58
GA + Epidural |         54        0.29       72.87
    GA+Spinal |         79        0.42       73.29
           LA |         74        0.39       73.68
LA + Sedation |      2,526       13.46       87.14
       Spinal |      2,412       12.86      100.00
---------------+-----------------------------------
        Total |     18,763      100.00

encode Anaestheticused, generate (Anaestheticusednum)
label list Anaestheticusednum

Anaestheticusednum:
           1  Unanswered
           2 Caudal
           3 GA
           4 GA + Caudal
           5 GA + Epidural
           6 GA+Spinal
           7 LA
           8 LA + Sedation
           9 Spinal

recode Anaestheticusednum 1=.
(Anaestheticusednum: 325 changes made)

tab Anaestheticusednum
  Anaesthetic |
          used |      Freq.     Percent        Cum.
---------------+-----------------------------------
       Caudal |          5        0.03        0.03
           GA |     12,945       70.21       70.24
  GA + Caudal |        343        1.86       72.10
GA + Epidural |         54        0.29       72.39
    GA+Spinal |         79        0.43       72.82
           LA |         74        0.40       73.22
LA + Sedation |      2,526       13.70       86.92
       Spinal |      2,412       13.08      100.00
---------------+-----------------------------------
        Total |     18,438      100.00
```

Section 7: Grade of operator

```
tab Gradeofoperator

      Grade of operator |      Freq.     Percent        Cum.
------------------------+-----------------------------------
             Unanswered |        264        1.41        1.41
   Associate Specialist |         64        0.34        1.75
             Consultant |     14,334       76.40       78.14
                  FTSTA |          7        0.04       78.18
                  Other |        189        1.01       79.19
Speciality Trainee (ST) |      2,556       13.62       92.81
            Staff grade |        202        1.08       93.89
  Subspec Trainee (SST) |      1,147        6.11      100.00
------------------------+-----------------------------------
                  Total |     18,763      100.00


encode Gradeofoperator, generate (Gradeofoperatornum)
label list Gradeofoperatornum
Gradeofoperatornum:
           1  Unanswered
           2 Associate Specialist
           3 Consultant
           4 FTSTA
           5 Other
           6 Speciality Trainee (ST)
           7 Staff grade
           8 Subspec Trainee (SST)

recode Gradeofoperatornum  1=.
(Gradeofoperatornum: 264 changes made)

tab Gradeofoperatornum
      Grade of operator |      Freq.     Percent        Cum.
------------------------+-----------------------------------
   Associate Specialist |         64        0.35        0.35
             Consultant |     14,334       77.49       77.83
                  FTSTA |          7        0.04       77.87
                  Other |        189        1.02       78.89
Speciality Trainee (ST) |      2,556       13.82       92.71
            Staff grade |        202        1.09       93.80
  Subspec Trainee (SST) |      1,147        6.20      100.00
------------------------+-----------------------------------
                  Total |     18,499      100.00

**this is to check the Chi 2 that I did for the previous paper

generate GradeforChi = 0 if Gradeofoperatornum ==3
(4,429 missing values generated)
replace GradeforChi = 1 if Gradeofoperatornum ==6|Gradeofoperatornum ==8
(3,703 real changes made)


* 0 = Consultant
* 1 = SST or ST

tab GradeforChi

GradeforChi |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |     14,334       79.47       79.47
          1 |      3,703       20.53      100.00
------------+-----------------------------------
      Total |     18,037      100.00
```

Section 8: Intra-op complications

Section 8a: Intra-op Bladder injury

```
tab IntraopBladderinjury

Intra-op-Bl |
      adder |
     injury |      Freq.     Percent        Cum.
------------+-----------------------------------
 Unanswered |        269        1.43        1.43
         No |     17,855       95.16       96.59
        Yes |        639        3.41      100.00
------------+-----------------------------------
      Total |     18,763      100.00


encode IntraopBladderinjury, generate (IntraopBladderinjurynum)
label list IntraopBladderinjurynum
IntraopBladderinjurynum:
           1  Unanswered
           2 No
           3 Yes



recode IntraopBladderinjurynum  1=.
**269changes made

tab IntraopBladderinjurynum

Intra-op-Bl |
      adder |
     injury |      Freq.     Percent        Cum.
------------+-----------------------------------
         No |     17,855       96.54       96.54
        Yes |        639        3.46      100.00
------------+-----------------------------------
      Total |     18,494      100.00

generate IntraopBladderinjuryforlogreg = 0 if IntraopBladderinjurynum ==3
*(18,124 missing values generated)
replace IntraopBladderinjuryforlogreg = 1 if IntraopBladderinjurynum ==2
*(17,855 real changes made)

tab IntraopBladderinjuryforlogreg

*0 = No,     1 = yes

IntraopBlad |
derinjuryfo |
    rlogreg |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        639        3.46        3.46
          1 |     17,855       96.54      100.00
------------+-----------------------------------
      Total |     18,494      100.00
```

Section 8b: Intra-op Ureteric injury

```
tab IntraopUretericinjury
Intra-op-Ur |
     eteric |
     injury |      Freq.     Percent        Cum.
------------+-----------------------------------
 Unanswered |        291        1.55        1.55
         No |     18,471       98.44       99.99
        Yes |          1        0.01      100.00
------------+-----------------------------------
      Total |     18,763      100.00



encode IntraopUretericinjury, generate (IntraopUretericinjurynum)
label list IntraopUretericinjurynum

IntraopUretericinjurynum:
           1  Unanswered
```

```
           2 No
           3 Yes

recode IntraopUretericinjurynum  1=.
(IntraopUretericinjurynum: 291 changes made)

tab IntraopUretericinjurynum

Intra-op-Ur |
     eteric |
     injury |      Freq.     Percent        Cum.
------------+-----------------------------------
         No |     18,471       99.99       99.99
        Yes |          1        0.01      100.00
------------+-----------------------------------
      Total |     18,472      100.00
```

Section 8c: Intra-op Vaginal Buttonholing

```
tab IntraopVaginalButtonholing
Intra-op-Va |
      ginal |
Button-holi |
         ng |      Freq.     Percent        Cum.
------------+-----------------------------------
 Unanswered |      7,446       39.68       39.68
         No |     11,260       60.01       99.70
        Yes |         57        0.30      100.00
------------+-----------------------------------
      Total |     18,763      100.00

       +--------------------------------------------------+


encode IntraopVaginalButtonholing, generate (IntraopVaginalButtonholingnum)
label list IntraopVaginalButtonholingnum
IntraopVaginalButtonholingnum:
           1  Unanswered
           2 No
           3 Yes

recode IntraopVaginalButtonholingnum  1=.
** 7446 changes made

tab IntraopVaginalButtonholingnum

Intra-op-Va |
      ginal |
Button-holi |
         ng |      Freq.     Percent        Cum.
------------+-----------------------------------
         No |     11,260       99.50       99.50
        Yes |         57        0.50      100.00
------------+-----------------------------------
      Total |     11,317      100.00
```

Section 8d: Intra-op Urethral injury

```
tab IntraopUrethralinjury
Intra-op-Ur |
     ethral |
     injury |      Freq.     Percent        Cum.
------------+-----------------------------------
 Unanswered |      7,446       39.68       39.68
         No |     11,303       60.24       99.93
        Yes |         14        0.07      100.00
------------+-----------------------------------
      Total |     18,763      100.00


recode  IntraopUrethralinjurynum 1=.
(IntraopUrethralinjurynum: 7446 changes made)

tab IntraopUrethralinjurynum
Intra-op-Ur |
     ethral |
```

```
     injury |      Freq.     Percent        Cum.
------------+-----------------------------------
         No |     11,303       99.88       99.88
        Yes |         14        0.12      100.00
------------+-----------------------------------
      Total |     11,317      100.00
```

Section 8e: Intra-op Vascular injury

```
tab IntraopVascularinjury
Intra-op-Va |
     scular |
     injury |      Freq.     Percent        Cum.
------------+-----------------------------------
 Unanswered |        294        1.57        1.57
         No |     18,458       98.37       99.94
        Yes |         11        0.06      100.00
------------+-----------------------------------
      Total |     18,763      100.00


encode IntraopVascularinjury, generate (IntraopVascularinjurynum)
label list IntraopVascularinjurynum

IntraopVascularinjurynum:
           1  Unanswered
           2 No
           3 Yes

recode  IntraopVascularinjurynum 1=.
(IntraopVascularinjurynum: 294 changes made)

tab IntraopVascularinjurynum
Intra-op-Va |
     scular |
     injury |      Freq.     Percent        Cum.
------------+-----------------------------------
         No |     18,458       99.94       99.94
        Yes |         11        0.06      100.00
------------+-----------------------------------
      Total |     18,469      100.00
```

Section 8f: Intra-op Neurological injury

```
tab IntraopNeurologicalinjury

Intra-op-Ne |
 urological |
     injury |      Freq.     Percent        Cum.
------------+-----------------------------------
 Unanswered |        294        1.57        1.57
         No |     18,467       98.42       99.99
        Yes |          2        0.01      100.00
------------+-----------------------------------
      Total |     18,763      100.00


encode IntraopNeurologicalinjury, generate (IntraopNeurologicalinjurynum)
label list IntraopNeurologicalinjurynum

IntraopNeurologicalinjurynum:
           1  Unanswered
           2 No
           3 Yes

recode IntraopNeurologicalinjurynum  1=.
(IntraopNeurologicalinjurynum: 294 changes made)

tab IntraopNeurologicalinjurynum
Intra-op-Ne |
 urological |
     injury |      Freq.     Percent        Cum.
------------+-----------------------------------
         No |     18,467       99.99       99.99
        Yes |          2        0.01      100.00
```

```
------------+-----------------------------------
      Total |     18,469      100.00
```

Section 8g: Intra-op Blood loss >500ml

```
tab IntraopBloodloss500ml

Intra-op-Bl |
 ood loss > |
      500ml |      Freq.     Percent        Cum.
------------+-----------------------------------
 Unanswered |        288        1.53        1.53
         No |     18,367       97.89       99.42
        Yes |        108        0.58      100.00
------------+-----------------------------------
      Total |     18,763      100.00


encode IntraopBloodloss500ml, generate (IntraopBloodloss500mlnum)
label list IntraopBloodloss500mlnum

IntraopBloodloss500mlnum:
           1  Unanswered
           2 No
           3 Yes

recode  IntraopBloodloss500mlnum 1=.
(IntraopBloodloss500mlnum: 288 changes made)

tab IntraopBloodloss500mlnum
Intra-op-Bl |
 ood loss > |
      500ml |      Freq.     Percent        Cum.
------------+-----------------------------------
         No |     18,367       99.42       99.42
        Yes |        108        0.58      100.00
------------+-----------------------------------
      Total |     18,475      100.00
```

Section 8h: Perioperative blood transfusion

```
tab Perioperativebloodtransfusion

Peri-operat |
  ive blood |
transfusion |      Freq.     Percent        Cum.
------------+-----------------------------------
 Unanswered |        292        1.56        1.56
         No |     18,452       98.34       99.90
        Yes |         19        0.10      100.00
------------+-----------------------------------
      Total |     18,763      100.00


encode Perioperativebloodtransfusion, generate (Perioperativebloodtransfusionnum)
label list Perioperativebloodtransfusionnum

Perioperativebloodtransfusionnum:
           1  Unanswered
           2 No
           3 Yes

recode Perioperativebloodtransfusionnum  1=.
(Perioperativebloodtransfusionnum: 292 changes made)

tab Perioperativebloodtransfusionnum
Peri-operat |
  ive blood |
transfusion |      Freq.     Percent        Cum.
------------+-----------------------------------
         No |     18,452       99.90       99.90
        Yes |         19        0.10      100.00
------------+-----------------------------------
      Total |     18,471      100.00
```

Section 8i: Perioperative Thromboembolism

```
tab PerioperativeThromboembolism

Peri-operat |
        ive |
Thromboembo |
       lism |      Freq.     Percent        Cum.
------------+-----------------------------------
 Unanswered |      2,585       13.78       13.78
         No |     16,174       86.20       99.98
        Yes |          4        0.02      100.00
------------+-----------------------------------
      Total |     18,763      100.00

encode PerioperativeThromboembolism, generate (PerioperativeThromboembolismnum)
label list PerioperativeThromboembolismnum
PerioperativeThromboembolismnum:
           1  Unanswered
           2 No
           3 Yes

recode  PerioperativeThromboembolismnum 1=.
(PerioperativeThromboembolismnum: 2585 changes made)

tab PerioperativeThromboembolismnum

Peri-operat |
        ive |
Thromboembo |
       lism |      Freq.     Percent        Cum.
------------+-----------------------------------
         No |     16,174       99.98       99.98
        Yes |          4        0.02      100.00
------------+-----------------------------------
      Total |     16,178      100.00
```

Section 8j: Death

```
tab Death

      Death |      Freq.     Percent        Cum.
------------+-----------------------------------
 Unanswered |      2,587       13.79       13.79
         No |     16,175       86.21       99.99
        Yes |          1        0.01      100.00
------------+-----------------------------------
      Total |     18,763      100.00


encode Death, generate (Deathnum)
label list Deathnum

Deathnum:
           1  Unanswered
           2 No
           3 Yes


recode Deathnum  1=.
(Deathnum: 2587 changes made)

tab Deathnum

      Death |      Freq.     Percent        Cum.
------------+-----------------------------------
         No |     16,175       99.99       99.99
        Yes |          1        0.01      100.00
------------+-----------------------------------
      Total |     16,176      100.00

**OperationDurationminutes - NOT IMPORTANT
```

Section 9: Length of stay Post Op

```
tab LengthofstayPostOp
```

Length of stay Post Op	Freq.	Percent	Cum.
1 day	3,470	18.49	18.49
2 days	1,860	9.91	28.41
3 days	408	2.17	30.58
4 days	138	0.74	31.32
5 days	21	0.11	31.43
6 days	10	0.05	31.48
7 days	3	0.02	31.50
8 days	2	0.01	31.51
Day case	2,880	15.35	46.86
Less than 24 hours	464	2.47	49.33
Outpatient	15	0.08	49.41
Unanswered	9,449	50.36	99.77
more than 4 days	43	0.23	100.00
Total	18,763	100.00	

Section 10: Return to theatre (RTT) for procedure related reason

```
tab RTTReturntotheatreforproced
```

RTT Return to theatre for procedure-related event within 72 hrs	Freq.	Percent	Cum.
Unanswered	5,753	30.66	30.66
No	12,919	68.85	99.52
Yes	91	0.48	100.00
Total	18,763	100.00	

```
encode RTTReturntotheatreforproced, generate (RTTReturntotheatreforprocednum)
label list RTTReturntotheatreforprocednum

RTTReturntotheatreforprocednum:
           1  Unanswered
           2 No
           3 Yes

recode RTTReturntotheatreforprocednum 1=.
(RTTReturntotheatreforprocednum: 5753 changes made)

tab RTTReturntotheatreforprocednum
```

RTT Return to theatre for procedure-related event within 72 hrs	Freq.	Percent	Cum.
No	12,919	99.30	99.30
Yes	91	0.70	100.00
Total	13,010	100.00	

Section 10a: RTT for Active bleeding

```
tab RTTActivebleeding
```

```
 RTT Active |
   bleeding |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.98       99.98
          Y |          4        0.02      100.00
------------+-----------------------------------
      Total |     16,951      100.00
```

```
encode RTTActivebleeding, generate (RTTActivebleedingnum)
label list RTTActivebleedingnum

RTTActivebleedingnum:
           1 N
           2 Y

** NO NEED TO recode RTTActivebleedingnum  =.

tab RTTActivebleedingnum
```

```
 RTT Active |
   bleeding |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.98       99.98
          Y |          4        0.02      100.00
------------+-----------------------------------
      Total |     16,951      100.00
```

Section 10b: RTT for Drainage of haematoma

```
tab RTTDrainageofhaematoma
```

```
        RTT |
Drainage of |
  haematoma |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.98       99.98
          Y |          3        0.02      100.00
------------+-----------------------------------
      Total |     16,950      100.00
```

```
encode RTTDrainageofhaematoma, generate (RTTDrainageofhaematomanum)
label list RTTDrainageofhaematomanum

RTTDrainageofhaematomanum:
           1 N
           2 Y

**NO NEED TO recode RTTDrainageofhaematomanum  =.

tab RTTDrainageofhaematomanum
```

```
        RTT |
Drainage of |
  haematoma |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.98       99.98
          Y |          3        0.02      100.00
------------+-----------------------------------
      Total |     16,950      100.00
```

Section 10c: RTT for Bladder injury

```
tab RTTBladderinjury
```

```
RTT Bladder |
     injury |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.99       99.99
          Y |          1        0.01      100.00
------------+-----------------------------------
      Total |     16,948      100.00
```

```
encode RTTBladderinjury, generate (RTTBladderinjurynum)
label list RTTBladderinjurynum

RTTBladderinjurynum:
           1 N
           2 Y

** NO NEED TO recode   =.

tab RTTBladderinjurynum

RTT Bladder |
     injury |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.99       99.99
          Y |          1        0.01      100.00
------------+-----------------------------------
      Total |     16,948      100.00
```

Section 10d: RTT for Ureteric injury

```
tab RTTUretericinjury

        RTT |
   Ureteric |
     injury |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947      100.00      100.00
------------+-----------------------------------
      Total |     16,947      100.00


encode RTTUretericinjury, generate (RTTUretericinjurynum)
label list RTTUretericinjurynum

RTTUretericinjurynum:
           1 N

**NO NEED TO recode   =.

tab RTTUretericinjurynum

        RTT |
   Ureteric |
     injury |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947      100.00      100.00
------------+-----------------------------------
      Total |     16,947      100.00
```

Section 10e: RTT for Voiding difficulty

```
tab RTTVoidingdifficulty

RTT Voiding |
 difficulty |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.99       99.99
          Y |          2        0.01      100.00
------------+-----------------------------------
      Total |     16,949      100.00


encode RTTVoidingdifficulty, generate (RTTVoidingdifficultynum)
label list RTTVoidingdifficultynum
RTTVoidingdifficultynum:
           1 N
           2 Y

** NO NEED TO recode   =.

tab RTTVoidingdifficultynum
```

```
RTT Voiding |
 difficulty |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.99       99.99
          Y |          2        0.01      100.00
------------+-----------------------------------
      Total |     16,949      100.00
```

Section 10f: RTT for Other

```
tab RTTOther
```

```
                              RTT Other |      Freq.     Percent        Cum.
----------------------------------------+-----------------------------------
             Blood patch for dural tap |          1       20.00       20.00
Emergency laparotomy for collapse/ret.. |          1       20.00       40.00
                        Removal of TVT |          1       20.00       60.00
TVT Loosening 29/10- still failed to .. |          1       20.00       80.00
                       loosening of tvt |          1       20.00      100.00
----------------------------------------+-----------------------------------
                                  Total |          5      100.00
```

```
encode RTTOther, generate (RTTOthernum)
label list RTTOthernum

RTTOthernum:
1 Blood patch for dural tap
2 Emergency laparotomy for collapse/retropubic haematoma post op- drainage/drain/2
unit transfusion
3 Removal of TVT
4 TVT Loosening 29/10- still failed to void- further indelling catheter X72 hrs
5 loosening of tvt


**NO NEED TO recode   =.

tab RTTOthernum
```

```
                              RTT Other |      Freq.     Percent        Cum.
----------------------------------------+-----------------------------------
             Blood patch for dural tap |          1       20.00       20.00
Emergency laparotomy for collapse/retro |          1       20.00       40.00
                        Removal of TVT |          1       20.00       60.00
TVT Loosening 29/10- still failed to vo |          1       20.00       80.00
                       loosening of tvt |          1       20.00      100.00
----------------------------------------+-----------------------------------
                                  Total |          5      100.00
```

Section 11: Catheterisation >10days

```
tab CatheterisationMoreThan10days
```

```
Catheterisa |
       tion |
   required |
   for more |
    than 10 |
       days |
    post-op |      Freq.     Percent        Cum.
------------+-----------------------------------
 Unanswered |      5,790       30.86       30.86
         No |     12,501       66.63       97.48
        Yes |        472        2.52      100.00
------------+-----------------------------------
      Total |     18,763      100.00
```

```
encode CatheterisationMoreThan10days, generate (CatheterisationMoreThan10daysnum)
label list CatheterisationMoreThan10daysnum

CatheterisationMoreThan10daysnum:
           1  Unanswered
           2 No
           3 Yes
```

```
recode  CatheterisationMoreThan10daysnum 1=.
(CatheterisationMoreThan10daysnum: 5790 changes made)

tab CatheterisationMoreThan10daysnum

Catheterisa |
       tion |
   required |
   for more |
    than 10 |
       days |
    post-op |      Freq.     Percent        Cum.
------------+-----------------------------------
         No |     12,501       96.36       96.36
        Yes |        472        3.64      100.00
------------+-----------------------------------
      Total |     12,973      100.00

Plannedcatheterisation
**ACTUALLY NEED TO LINK THIS TO CatheterisationMoreThan10daysnum**
tab
encode , generate (num)
label list num
recode   =.
tab num
**FailedTWOC  **ACTUALLY NEED TO LINK TO CatheterisationMoreThan10daysnum**
tab
encode , generate (num)
label list num
recode   =.
tab num
**IndwellingCathAfterBladdeInjury
**ACTUALLY NEED TO LINK TO CatheterisationMoreThan10daysnum**
tab
encode , generate (num)
label list num
recode   =.
tab num
**Cath10daysOther**ACTUALLY NEED TO LINK  TO CatheterisationMoreThan10daysnum**
tab
encode , generate (num)
label list num
recode   =.
tab num
```

Section 12: Return to hospital (RTH) within 30 days

```
tab RTHReturntohospitalwithin30

  RTH Return to |
hospital within |
    30 days for |
      procedure |
  related event |      Freq.     Percent        Cum.
----------------+-----------------------------------
     Unanswered |     17,699       94.33       94.33
             No |        976        5.20       99.53
 Yes - Elective |         56        0.30       99.83
Yes - Emergency |         32        0.17      100.00
----------------+-----------------------------------
          Total |     18,763      100.00

encode RTHReturntohospitalwithin30, generate (RTHReturntohospitalwithin30num)
label list RTHReturntohospitalwithin30num

RTHReturntohospitalwithin30num:
           1  Unanswered
           2 No
           3 Yes - Elective
           4 Yes - Emergency

recode RTHReturntohospitalwithin30num 1=.
(RTHReturntohospitalwithin30num: 17699 changes made)

tab RTHReturntohospitalwithin30num
  RTH Return to |
```

```
hospital within |
    30 days for |
      procedure |
  related event |      Freq.     Percent        Cum.
----------------+-----------------------------------
             No |        976       91.73       91.73
 Yes - Elective |         56        5.26       96.99
Yes - Emergency |         32        3.01      100.00
----------------+-----------------------------------
          Total |      1,064      100.00
```

```
generate RTHReturntohospital30numlogreg = 0 if RTHReturntohospitalwithin30num ==2
*(17,787 missing values generated)
replace RTHReturntohospital30numlogreg = 1 if RTHReturntohospitalwithin30num
==3|RTHReturntohospitalwithin30num ==4
*(8 real changes made)

tab RTHReturntohospital30numlogreg
```

```
RTHReturnto |
hospital30n |
   umlogreg |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        976       91.73       91.73
          1 |         88        8.27      100.00
------------+-----------------------------------
      Total |      1,064      100.00
```

Section 12a: RTH for TWOC

```
tab RTHTWOC
```

```
  RTH Trial |
    without |
   catheter |
      (TWOC |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.72       99.72
          Y |         47        0.28      100.00
------------+-----------------------------------
      Total |     16,994      100.00
```

```
encode RTHTWOC, generate (RTHTWOCnum)
label list RTHTWOCnum

RTHTWOCnum:
           1 N
           2 Y

**NO NEED TO recode   =.

tab RTHTWOCnum
```

```
  RTH Trial |
    without |
   catheter |
      (TWOC |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.72       99.72
          Y |         47        0.28      100.00
------------+-----------------------------------
      Total |     16,994      100.00
```

Section 12b: RTH for Voiding difficulty

```
tab RTHVoidingdifficulty
```

```
RTH Voiding |
 difficulty |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.95       99.95
          Y |          8        0.05      100.00
------------+-----------------------------------
      Total |     16,955      100.00
```

```
encode RTHVoidingdifficulty, generate (RTHVoidingdifficultynum)
label list RTHVoidingdifficultynum

RTHVoidingdifficultynum:
           1 N
           2 Y

**NO NEED TO recode   =.

tab RTHVoidingdifficultynum


RTH Voiding |
 difficulty |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.95       99.95
          Y |          8        0.05      100.00
------------+-----------------------------------
      Total |     16,955      100.00
```

Section 12c: RTH for Constipation

```
tab RTHConstipation

        RTH |
Constipatio |
          n |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.99       99.99
          Y |          1        0.01      100.00
------------+-----------------------------------
      Total |     16,948      100.00


encode RTHConstipation, generate (RTHConstipationnum)
label list RTHConstipationnum
RTHConstipationnum:
           1 N
           2 Y

** NO NEED TO recode RTHConstipationnum  =.

tab RTHConstipationnum
       RTH |
Constipatio |
          n |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.99       99.99
          Y |          1        0.01      100.00
------------+-----------------------------------
      Total |     16,948      100.00
```

Section 12d: RTH Infection

```
tab RTHInfection

        RTH |
  Infection |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.95       99.95
          Y |          9        0.05      100.00
------------+-----------------------------------
      Total |     16,956      100.00


encode RTHInfection, generate (RTHInfectionnum)
label list RTHInfectionnum

RTHInfectionnum:
           1 N
           2 Y

**NO NEED TO recode   =.

tab RTHInfectionnum
```

```
        RTH |
  Infection |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.95       99.95
          Y |          9        0.05      100.00
------------+-----------------------------------
      Total |     16,956      100.00
```

Section 12e: RTH for Active bleeding

```
tab RTHActivebleeding

 RTH Active |
   bleeding |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.98       99.98
          Y |          3        0.02      100.00
------------+-----------------------------------
      Total |     16,950      100.00


encode RTHActivebleeding, generate (RTHActivebleedingnum)
label list RTHActivebleedingnum

RTHActivebleedingnum:
           1 N
           2 Y

**NO NEED TO recode   =.

tab RTHActivebleedingnum
 RTH Active |
   bleeding |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.98       99.98
          Y |          3        0.02      100.00
------------+-----------------------------------
      Total |     16,950      100.00
```

Section 12f: RTH Haematoma

```
tab RTHHaematoma
        RTH |
  Haematoma |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.97       99.97
          Y |          5        0.03      100.00
------------+-----------------------------------
      Total |     16,952      100.00


encode RTHHaematoma, generate (RTHHaematomanum)
label list RTHHaematomanum
RTHHaematomanum:
           1 N
           2 Y

**NO NEED TO recode   =.

tab RTHHaematomanum
        RTH |
  Haematoma |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.97       99.97
          Y |          5        0.03      100.00
------------+-----------------------------------
      Total |     16,952      100.00
```

Section 12g: RTH for Bladder injury

```
tab RTHBladderinjury

RTH Bladder |
     injury |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947      100.00      100.00
```

```
------------+-----------------------------------
      Total |     16,947      100.00


encode RTHBladderinjury, generate (RTHBladderinjurynum)
label list RTHBladderinjurynum
RTHBladderinjurynum:
           1 N

**NO NEED TO recode   =.

tab RTHBladderinjurynum
RTH Bladder |
     injury |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947      100.00      100.00
------------+-----------------------------------
      Total |     16,947      100.00
```

Section 12h: RTH for Ureteric injury

```
tab RTHUretericinjury
        RTH |
   Ureteric |
     injury |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947      100.00      100.00
------------+-----------------------------------
      Total |     16,947      100.00



encode RTHUretericinjury, generate (RTHUretericinjurynum)
label list RTHUretericinjurynum

RTHUretericinjurynum:
           1 N

**NO NEEED TO recode   =.

tab RTHUretericinjurynum
        RTH |
   Ureteric |
     injury |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947      100.00      100.00
------------+-----------------------------------
      Total |     16,947      100.00
```

Section 12i: RTH for Other

```
tab RTHOther

                              RTH Other |      Freq.     Percent        Cum.
----------------------------------------+-----------------------------------
Admitted 2 days post op in retention... |          1        3.03        3.03
Admitted WRH- further TVT loosening a.. |          1        3.03        6.06
     Catheter 5 days. Succcessful TWOC. |          1        3.03        9.09
                                    DVT |          1        3.03       12.12
Fainted and vomitted at home after di.. |          1        3.03       15.15
                                    NAD |          2        6.06       21.21
Not feeling right - felt as though so.. |          1        3.03       24.24
                                   PAIN |          1        3.03       27.27
                                   Pain |          1        3.03       30.30
      Pain (after 3/52) No cause found. |          1        3.03       33.33
       Pain in groinSettled at 3 months |          1        3.03       36.36
Post op urinary retention. Succesful .. |          1        3.03       39.39
Slight PV dicharge from repair site- .. |          1        3.03       45.45
    Some pain, examined NAD, reassured. |          1        3.03       48.48
                     Successful on day 6 |          1        3.03       51.52
Symptoms of overactive bladder on Ves.. |          1        3.03       54.55
                              TVT strech |          1        3.03       57.58
                                 TWOC x2 |          1        3.03       60.61
                URINARY TRACT INFECTION |          1        3.03       63.64
              Urinary retention and ISC |          1        3.03       66.67
```

```
  admitted to another hospital with UTI |          1        3.03       69.70
bleeding subsided. Brown spotting whe.. |          1        3.03       72.73
c/o offensive PV discharge. Exam NAD... |          1        3.03       75.76
                           failed twoc |          1        3.03       78.79
felt as though she had vaginal infect.. |          1        3.03       81.82
                            groin pain |          1        3.03       84.85
in dwelling catheter for one week rem.. |          1        3.03       87.88
patient was worried she could feel so.. |          1        3.03       90.91
presented with mild bleeding- obs nor.. |          1        3.03       93.94
                        review in clinic |          1        3.03       96.97
          succesful TWOC 4 DAYS POST OP |          1        3.03      100.00
----------------------------------------+-----------------------------------
                                  Total |         33      100.00
```

Section 13: Readmitted to hospital (RdTH) within 30 days

```
tab RdTHReadmittedtohospital30dy
```

```
 RdTH Readmitted to |
 hospital within 30 |
 days for procedure |
      related event |      Freq.     Percent        Cum.
--------------------+-----------------------------------
         Unanswered |      5,989       31.92       31.92
                 No |     12,139       64.70       96.62
     Yes - Elective |         10        0.05       96.67
    Yes - Emergency |         13        0.07       96.74
Yes - Not specified |        612        3.26      100.00
--------------------+-----------------------------------
              Total |     18,763      100.00
```

```
encode RdTHReadmittedtohospital30dy, generate (RdTHReadmittedtohospital30dynum)
label list RdTHReadmittedtohospital30dynum

RdTHReadmittedtohospital30dynum:
           1  Unanswered
           2 No
           3 Yes - Elective
           4 Yes - Emergency
           5 Yes - Not specified


recode  RdTHReadmittedtohospital30dynum 1=.
*(RdTHReadmittedtohospital30dynum: 5989 changes made)

tab RdTHReadmittedtohospital30dynum
```

```
 RdTH Readmitted to |
 hospital within 30 |
 days for procedure |
      related event |      Freq.     Percent        Cum.
--------------------+-----------------------------------
                 No |     12,139       95.03       95.03
     Yes - Elective |         10        0.08       95.11
    Yes - Emergency |         13        0.10       95.21
Yes - Not specified |        612        4.79      100.00
--------------------+-----------------------------------
              Total |     12,774      100.00
```

Section 13a: RdTH for TWOC

```
tab RdTHTWOC
```

```
 RdTH Trial |
    without |
   catheter |
      (TWOC |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.97       99.97
          Y |          5        0.03      100.00
------------+-----------------------------------
      Total |     16,952      100.00
```

```
encode RdTHTWOC, generate (RdTHTWOCnum)
```

```
label list RdTHTWOCnum

RdTHTWOCnum:
           1 N
           2 Y

**NO NEED TO recode   =.

tab RdTHTWOCnum

 RdTH Trial |
    without |
   catheter |
      (TWOC |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.97       99.97
          Y |          5        0.03      100.00
------------+-----------------------------------
      Total |     16,952      100.00
```

Section 13b: RdTH for Voiding difficulty

```
tab RdTHVoidingdifficulty
       RdTH |
    Voiding |
 difficulty |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.98       99.98
          Y |          3        0.02      100.00
------------+-----------------------------------
      Total |     16,950      100.00


encode RdTHVoidingdifficulty, generate (RdTHVoidingdifficultynum)
label list RdTHVoidingdifficultynum

RdTHVoidingdifficultynum:
           1 N
           2 Y
**NO NEED TO recode RdTHVoidingdifficultynum  =.

tab RdTHVoidingdifficultynum
       RdTH |
    Voiding |
 difficulty |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.98       99.98
          Y |          3        0.02      100.00
------------+-----------------------------------
      Total |     16,950      100.00
```

Section 13c: RdTH for Constipation

```
tab RdTHConstipation

       RdTH |
Constipatio |
          n |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947      100.00      100.00
------------+-----------------------------------
      Total |     16,947      100.00


encode RdTHConstipation, generate (RdTHConstipationnum)
label list RdTHConstipationnum
RdTHConstipationnum:
           1 N
*NO NEED TO recode RdTHConstipationnum  =.

tab RdTHConstipationnum

       RdTH |
Constipatio |
```

```
          n |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947      100.00      100.00
------------+-----------------------------------
      Total |     16,947      100.00
```

Section 13d: RdTH for Infection

```
tab RdTHInfection


       RdTH |
  Infection |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.98       99.98
          Y |          3        0.02      100.00
------------+-----------------------------------
      Total |     16,950      100.00


encode RdTHInfection, generate (RdTHInfectionnum)
label list RdTHInfectionnum

RdTHInfectionnum:
           1 N
           2 Y
**NO NEED TO recode RdTHInfectionnum  =.

tab RdTHInfectionnum
       RdTH |
  Infection |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.98       99.98
          Y |          3        0.02      100.00
------------+-----------------------------------
      Total |     16,950      100.00
```

Section 13e: RdTH for Active bleeding

```
tab RdTHActivebleeding
RdTH Active |
   bleeding |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947      100.00      100.00
------------+-----------------------------------
      Total |     16,947      100.00


encode RdTHActivebleeding, generate (RdTHActivebleedingnum)
label list RdTHActivebleedingnum
RdTHActivebleedingnum:
           1 N
**NO NEED TO recode RdTHActivebleedingnum  =.

tab RdTHActivebleedingnum

RdTH Active |
   bleeding |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947      100.00      100.00
------------+-----------------------------------
      Total |     16,947      100.00
```

Section 13f: RdTH for Haematoma

```
tab RdTHHaematoma

       RdTH |
  Haematoma |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.98       99.98
          Y |          3        0.02      100.00
------------+-----------------------------------
      Total |     16,950      100.00

encode RdTHHaematoma, generate (RdTHHaematomanum)
label list RdTHHaematomanum
```

```
RdTHHaematomanum:
           1 N
           2 Y

**NO NEED TO recode RdTHHaematomanum  =.

tab RdTHHaematomanum
       RdTH |
  Haematoma |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947       99.98       99.98
          Y |          3        0.02      100.00
------------+-----------------------------------
      Total |     16,950      100.00
```

Section 13g: RdTH for Bladder injury

```
tab RdTHBladderinjury

       RdTH |
    Bladder |
     injury |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947      100.00      100.00
------------+-----------------------------------
      Total |     16,947      100.00

encode RdTHBladderinjury, generate (RdTHBladderinjurynum)
label list RdTHBladderinjurynum

RdTHBladderinjurynum:
           1 N
**NO NEED TO recode RdTHBladderinjurynum  =.

tab RdTHBladderinjurynum

       RdTH |
    Bladder |
     injury |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947      100.00      100.00
------------+-----------------------------------
      Total |     16,947      100.00
```

Section 13h: RdTH for Ureteric injury

```
tab RdTHUretericinjury

       RdTH |
   Ureteric |
     injury |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947      100.00      100.00
------------+-----------------------------------
      Total |     16,947      100.00


encode RdTHUretericinjury, generate (RdTHUretericinjurynum)
label list RdTHUretericinjurynum

RdTHUretericinjurynum:
           1 N
**NO NEED TO recode RdTHUretericinjurynum  =.

tab RdTHUretericinjurynum

       RdTH |
   Ureteric |
     injury |      Freq.     Percent        Cum.
------------+-----------------------------------
          N |     16,947      100.00      100.00
------------+-----------------------------------
      Total |     16,947      100.00
```

Section 13i: RdTH for Other

```
tab RdTHOther

encode RdTHOther, generate (RdTHOthernum)
label list RdTHOthernum

RdTHOthernum:
1 Admitted WRH- further TVT loosening and SPCAwaiting TWOC- if fails - for
cutting/removal suburethral TVTCutting/removal of suburethral TVT on 17/11 and then
CISC teaching
2 Difficulty voiding postop. Failed TWOC x2. Tape loosened under LA day 7. Successful.
3 Division of TVT mesh vaginally at day 8 post-operative as per patient request. She
declined stretching of TVT mesh and opt for division.
4 Multiple PE
5 Pain - CT scan with no haematoma seen
6 TVT loosened on day 7.
7 Vaginal tape exposure a few days after surgeryResutured
8 division of tape for long term voiding problems
9 groin pain
10 groin pain
11 lossening of mid urethral sling on 27/08/2015, tape found to have narrowed and
rolled upflattened out and tension released
```

Section 14: Follow up method

```
tab Howwasfollowupcarriedout
```

How was follow-up carried out	Freq.	Percent	Cum.
Unanswered	6,550	34.91	34.91
As per local agreement	17	0.09	35.00
GP Practice	84	0.45	35.45
Online	12	0.06	35.51
Outpatient visit	9,676	51.57	87.08
Postal questionnaire	1,356	7.23	94.31
Telephone response	1,068	5.69	100.00
Total	18,763	100.00	

```
encode Howwasfollowupcarriedout, generate (Howwasfollowupcarriedoutnum)
label list Howwasfollowupcarriedoutnum

Howwasfollowupcarriedoutnum:
           1  Unanswered
           2 As per local agreement
           3 GP Practice
           4 Online
           5 Outpatient visit
           6 Postal questionnaire
           7 Telephone response

recode Howwasfollowupcarriedoutnum  1=.
*(Howwasfollowupcarriedoutnum: 6550 changes made)

tab Howwasfollowupcarriedoutnum
```

How was follow-up carried out	Freq.	Percent	Cum.
As per local agreement	17	0.14	0.14
GP Practice	84	0.69	0.83
Online	12	0.10	0.93
Outpatient visit	9,676	79.23	80.15
Postal questionnaire	1,356	11.10	91.26
Telephone response	1,068	8.74	100.00
Total	12,213	100.00	

Section 15: Follow up interval

```
tab Whatisthefollowupinterval
```

What is the follow-up interval	Freq.	Percent	Cum.
Unanswered	6,779	36.13	36.13
12 Months	427	2.28	38.41
3 Months	4,137	22.05	60.45
6 Months	3,363	17.92	78.38
6 Weeks	4,057	21.62	100.00
Total	18,763	100.00	

```
encode Whatisthefollowupinterval, generate (Whatisthefollowupintervalnum)
label list Whatisthefollowupintervalnum

Whatisthefollowupintervalnum:
           1  Unanswered
           2 12 Months
           3 3 Months
           4 6 Months
           5 6 Weeks

recode  Whatisthefollowupintervalnum 1=.
```

```
*(Whatisthefollowupintervalnum: 6779 changes made)

tab Whatisthefollowupintervalnum

What is the |
  follow-up |
   interval |      Freq.     Percent        Cum.
------------+-----------------------------------
  12 Months |         427        3.56        3.56
   3 Months |       4,137       34.52       38.08
   6 Months |       3,363       28.06       66.15
    6 Weeks |       4,057       33.85      100.00
------------+-----------------------------------
      Total |      11,984      100.00
```

Section 16: Patient Reported Outcomes

Section 16a: PGII

```
*Find out what the GIII looks like

tab GIIIncontinence

 Global Impression |
of Improvement for |
      Incontinence |      Freq.     Percent        Cum.
-------------------+-----------------------------------
      0-Unanswered |      7,397       39.42       39.42
1-Very much better |      8,349       44.50       83.92
     2-Much better |      1,990       10.61       94.53
 3-A little better |        553        2.95       97.47
       4-No change |        285        1.52       98.99
  5-A little worse |         74        0.39       99.39
      6-Much worse |         78        0.42       99.80
 7-Very much worse |         37        0.20      100.00
-------------------+-----------------------------------
             Total |     18,763      100.00

encode GIIIncontinence, generate (GIIInum)
label list GIIInum

GIIInum:
           1 0-Unanswered
           2 1-Very much better
           3 2-Much better
           4 3-A little better
           5 4-No change
           6 5-A little worse
           7 6-Much worse
           8 7-Very much worse

*Remove unanswered

recode GIIInum  1=.
*(GIIInum: 7397 changes made)

*Find out what the GIII looks like without unanswered

tab GIIInum
 Global Impression |
of Improvement for |
      Incontinence |      Freq.     Percent        Cum.
-------------------+-----------------------------------
1-Very much better |      8,349       73.46       73.46
     2-Much better |      1,990       17.51       90.96
 3-A little better |        553        4.87       95.83
       4-No change |        285        2.51       98.34
  5-A little worse |         74        0.65       98.99
      6-Much worse |         78        0.69       99.67
 7-Very much worse |         37        0.33      100.00
-------------------+-----------------------------------
             Total |     11,366      100.00

* Group the others into groups


recode GIIInum 1=. 2=1 3=1 4=2 5=2 6=3 7=3 8=3
(GIIInum: 11366 changes made)

* Change the names of the groups

label define GIIInum 1 "Better", modify
label define GIIInum 2 "No change", modify
label define GIIInum 3 "Worse", modify

tab GIIInum

Global Impression |
   of Improvement |
 for Incontinence |      Freq.     Percent        Cum.
------------------+-----------------------------------
```

```
           Better |     10,339       90.96       90.96
        No change |        838        7.37       98.34
            Worse |        189        1.66      100.00
------------------+-----------------------------------
            Total |     11,366      100.00
```

```
*For making binary outcome

generate GIIIforlogreg = 0 if GIIInum ==1
(8,424 missing values generated)

replace GIIIforlogreg = 1 if GIIInum ==2|GIIInum ==3
(1,027 real changes made)

tab GIIIforlogreg

GIIIforlogr |
         eg |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |     10,339       90.96       90.96
          1 |      1,027        9.04      100.00
------------+-----------------------------------
      Total |     11,366      100.00
```

Section 16b: Change in Stress Urinary Incontinence

```
tab ChangeinStressUrinaryInconti
    Change in |
       Stress |
      Urinary |
 Incontinence |      Freq.     Percent        Cum.
--------------+-----------------------------------
   Unanswered |      8,077       43.05       43.05
        Cured |      8,288       44.17       87.22
     Improved |      1,808        9.64       96.86
Never present |        239        1.27       98.13
    No change |        288        1.53       99.66
        Worse |         62        0.33       99.99
          n/a |          1        0.01      100.00
--------------+-----------------------------------
        Total |     18,763      100.00

encode ChangeinStressUrinaryInconti, generate (ChangeinStressUrinaryIncontinum)
label list ChangeinStressUrinaryIncontinum

           1  Unanswered
           2 Cured
           3 Improved
           4 Never present
           5 No change
           6 Worse
           7 n/a

recode  ChangeinStressUrinaryIncontinum 1=.
 (ChangeinStressUrinaryIncontinum: 8077 changes made)

recode ChangeinStressUrinaryIncontinum 7=.
(ChangeinStressUrinaryIncontinum: 1 changes made)

 tab ChangeinStressUrinaryIncontinum

    Change in |
       Stress |
      Urinary |
 Incontinence |      Freq.     Percent        Cum.
--------------+-----------------------------------
        Cured |      8,288       77.57       77.57
     Improved |      1,808       16.92       94.49
Never present |        239        2.24       96.72
    No change |        288        2.70       99.42
        Worse |         62        0.58      100.00
--------------+-----------------------------------
        Total |     10,685      100.00

               **log reg**
generate changesuiforlogreg = 0 if ChangeinStressUrinaryIncontinum == 2|
ChangeinStressUrinaryIncontinum == 3
(8,667 missing values generated)

replace changesuiforlogreg = 1 if ChangeinStressUrinaryIncontinum ==5|
ChangeinStressUrinaryIncontinum ==6
(350 real changes made)

* 0 = cured/improved
* 1 = no change/worse
* removed never present and unanswered

tab changesuiforlogreg

changesuifo |
    rlogreg |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |     10,096       96.65       96.65
          1 |        350        3.35      100.00
------------+-----------------------------------
      Total |     10,446      100.00
```

Section 16c: Change in OAB

```
tab ChangeinUrgencyUrgeInconti
    Change in |
    Urgency / |
         Urge |
 Incontinence |      Freq.     Percent        Cum.
--------------+-----------------------------------
   Unanswered |      8,473       45.16       45.16
        Cured |      1,635        8.71       53.87
     Improved |      2,408       12.83       66.71
Never present |      3,670       19.56       86.27
  New symptom |        396        2.11       88.38
    No change |      1,573        8.38       96.76
        Worse |        608        3.24      100.00
--------------+-----------------------------------
        Total |     18,763      100.00

encode ChangeinUrgencyUrgeInconti, generate (ChangeinUrgencyUrgeIncontinum)
label list ChangeinUrgencyUrgeIncontinum
ChangeinUrgencyUrgeIncontinum:
           1  Unanswered
           2 Cured
           3 Improved
           4 Never present
           5 New symptom
           6 No change
           7 Worse

recode  ChangeinUrgencyUrgeIncontinum 1=.
 (ChangeinUrgencyUrgeIncontinum: 8473 changes made)

tab ChangeinUrgencyUrgeIncontinum
    Change in |
    Urgency / |
         Urge |
 Incontinence |      Freq.     Percent        Cum.
--------------+-----------------------------------
        Cured |      1,635       15.89       15.89
     Improved |      2,408       23.40       39.29
Never present |      3,670       35.67       74.96
  New symptom |        396        3.85       78.80
    No change |      1,573       15.29       94.09
        Worse |        608        5.91      100.00
--------------+-----------------------------------
        Total |     10,290      100.00

**FOR LOG REG**Need to do this in 3 different ways - 1. new symptom vs others, 2.
worse vs others 3. newsymtom and worse vs others

changeuuiforlogregns     changeuuiforlogregwor      changeuuiforlogregnswor

*1: 0 = new symptoms
generate changeuuiforlogregns = 0 if ChangeinUrgencyUrgeIncontinum == 5
(18,367 missing values generated)
replace changeuuiforlogregns = 1 if ChangeinUrgencyUrgeIncontinum ==
2|ChangeinUrgencyUrgeIncontinum == 3|ChangeinUrgencyUrgeIncontinum ==
4|ChangeinUrgencyUrgeIncontinum == 6| ChangeinUrgencyUrgeIncontinum ==7
(9,894 real changes made)

*0 = new symptom  1 = not new symptom
tab changeuuiforlogregns
changeuuifo |
  rlogregns |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        396        3.85        3.85
          1 |      9,894       96.15      100.00
------------+-----------------------------------
      Total |     10,290      100.00

*2: 0 = worse
generate changeuuiforlogregwor = 0 if ChangeinUrgencyUrgeIncontinum == 7
(18,155 missing values generated)

replace changeuuiforlogregwor = 1 if ChangeinUrgencyUrgeIncontinum ==
2|ChangeinUrgencyUrgeIncontinum == 3|ChangeinUrgencyUrgeIncontinum ==
4|ChangeinUrgencyUrgeIncontinum == 5| ChangeinUrgencyUrgeIncontinum ==6
```

```
(9,682 real changes made)

*0 = worse 1 = not worse

tab changeuuiforlogregwor

changeuuifo |
   rlogregw |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        608        5.91        5.91
          1 |      9,682       94.09      100.00
------------+-----------------------------------
      Total |     10,290      100.00


*This is now doing it again removing never present and new symptom
*0=worse 1=not worse
generate changeuuiforlogregworactual = 0 if  ChangeinUrgencyUrgeIncontinum == 7
(18,155 missing values generated)

replace changeuuiforlogregworactual = 1 if ChangeinUrgencyUrgeIncontinum ==
2|ChangeinUrgencyUrgeIncontinum == 3|ChangeinUrgencyUrgeIncontinum == 6
          (5,616 real changes made)

tab changeuuiforlogregworactual



changeuuifo |
rlogregwora |
      ctual |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |        608        9.77        9.77
          1 |      5,616       90.23      100.00
------------+-----------------------------------
      Total |      6,224      100.00


*3: 0 = newsypmtom and worse
generate changeuuiforlogregnswor = 0 if ChangeinUrgencyUrgeIncontinum == 5|
ChangeinUrgencyUrgeIncontinum == 7
(17,759 missing values generated)

replace changeuuiforlogregnswor = 1 if ChangeinUrgencyUrgeIncontinum ==
2|ChangeinUrgencyUrgeIncontinum == 3|ChangeinUrgencyUrgeIncontinum == 4|
ChangeinUrgencyUrgeIncontinum ==6
(9,286 real changes made)

*0 = new symptom and worse 1 = not new symptoms and worse

tab changeuuiforlogregnswor
changeuuifo |
  rlogregwn |      Freq.     Percent        Cum.
------------+-----------------------------------
          0 |      1,004        9.76        9.76
          1 |      9,286       90.24      100.00
------------+-----------------------------------
      Total |     10,290      100.00
```

Section 17: Does patient require catheter

```
tab FuDoespatientrequirecathete

     F/u Does |
      patient |
      require |
    catheters |      Freq.     Percent        Cum.
--------------+-----------------------------------
   Unanswered |      8,392       45.14       45.14
Never present |          1        0.01       45.15
           No |     10,177       54.74       99.89
   Yes - CISC |         19        0.10       99.99
    Yes - SPC |          2        0.01      100.00
--------------+-----------------------------------
        Total |     18,591      100.00


encode FuDoespatientrequirecathete, generate (FuDoespatientrequirecathetenum)
label list FuDoespatientrequirecathetenum

FuDoespatientrequirecathetenum:
           1  Unanswered
           2 Never present
           3 No
           4 Yes - CISC
           5 Yes - SPC

recode  FuDoespatientrequirecathetenum 1=.
(FuDoespatientrequirecathetenum: 8392 changes made)

tab FuDoespatientrequirecathetenum
    F/u Does |
      patient |
      require |
    catheters |      Freq.     Percent        Cum.
--------------+-----------------------------------
Never present |          1        0.01        0.01
           No |     10,177       99.78       99.79
   Yes - CISC |         19        0.19       99.98
    Yes - SPC |          2        0.02      100.00
--------------+-----------------------------------
        Total |     10,199      100.00
```

Section 18: Comparisons

Section 18a: Age vs BMI

```
tab Agegrouped BMIgrouped,
```

Age at op	BMI							
	15-<18	18-<25	25-<30	30-<35	35-<40	40-<45	45-<50	50-<65	Total
18-<50	8	1,648	2,075	1,306	589	159	41	13	5,839
50-<75	5	1,137	2,045	1,345	553	163	49	10	5,307
75-100	0	103	191	119	39	8	2	1	463
Total	13	2,888	4,311	2,770	1,181	330	92	24	11,609

Section 18b: Age vs UDS

```
tab Agegrouped PreOpUDSChi ,
```

Age at op	Pre-op Urodynamic diagnosis			Total
	USI	USI+vd	AnyDO	
18-<50	6,697	158	1,270	8,125
50-<75	5,658	231	1,383	7,272
75-100	470	37	142	649
Total	12,825	426	2,795	16,046

Section 18c: BMI vs grade of operator

```
tab BMIgrouped Gradeofoperatornum,
```

BMI	Grade of operator							Total
	Associate	Consultan	FTSTA	Other	Specialit	Staff gra	Subspec T	
15-<18	0	10	0	0	1	1	1	13
18-<25	5	2,298	1	33	357	37	187	2,918
25-<30	21	3,376	1	58	564	48	299	4,367
30-<35	18	2,135	1	26	399	43	192	2,814
35-<40	9	915	0	17	160	13	86	1,200
40-<45	1	273	1	1	36	6	16	334
45-<50	0	77	0	1	10	1	3	92
50-<65	0	21	0	0	2	0	0	23
Total	54	9,105	4	136	1,529	149	784	11,761

Section 18d: BMI vs UDS

```
tab PreOpUDSDes BMIgrouped
```

Pre-op Urodynamic diagnosis	BMI								Total
	15-<18	18-<25	25-<30	30-<35	35-<40	40-<45	45-<50	50-<65	
USI	6	2,245	3,263	2,021	825	230	62	15	8,667
USI and voiding dysfu	1	63	106	69	30	6	4	2	281
Mixed	2	292	547	438	235	70	18	5	1,607
Mixed and voiding dys	0	10	14	19	5	4	0	1	53
DOA	0	11	22	13	7	1	1	0	55
Normal	1	111	118	70	16	4	1	0	321
Voiding dysfunction	0	2	3	3	0	0	0	0	8
Total	10	2,734	4,073	2,633	1,118	315	86	23	10,992

```
tab BMIgrouped PreOpUDSChi ,
```

BMI	Pre-op Urodynamic diagnosis			Total
	USI	USI+vd	AnyDO	
15-<18	6	1	2	9
18-<25	2,245	63	313	2,621
25-<30	3,265	104	583	3,952
30-<35	2,022	68	470	2,560
35-<40	826	29	247	1,102
40-<45	230	6	75	311
45-<50	62	4	19	85
50-<65	15	2	6	23
Total	8,671	277	1,715	10,663

```
*****************************************************************************
*                                                                           *
*        STATS RESULTS                                                      *
*                                                                           *
*                                                                           *
*****************************************************************************

*OUTCOMES
*1. Global Impression of Incontinence
*Improved (VMB&MB)  vs   No change (LB/NoCh) vs  Worse (LW/MW/VMW)  -  Chi
*
*Improved vs not improved - regression
*
*2. Change in Stress Urinary Incontinence
*
*Cured/Improved     vs      No change/Worse
*
*dichotomise to improved/cured vs not - regression
*remove never present - comment in text
*
*3. Change in Urgency Urge Incontinence
*a. New
*b. Worse
*c. New and worse
*
*
*4. Complications ????as a variable and an outcome
*
* Bladder injury = 639
* Urethral injury = 14
* Ureteric injury = 1
* Vaginal buttonholing = 57
* Vascular injury = 11
* Neurological injury = 2

* Intraop graft complication y/n = 32
* Intraop graft complication gcc = 23
* Blood loss >500 ml = 108 - do this by grade
* Transfusion = 19
* Death = 1

* Return to theatre within 72 hours = 91
* Catheterisation for more than 10 days = 472 - do this by UDS
* Return to Hospital within 30 days - 88
* Thromboembolism = 4

*VARIABLES

*Age    continuously
*Physio Yes/No
*UDS
*BMI    continuously?
*Grade of operator


* Bladder injury = 639
* Urethral injury = 14
* Ureteric injury = 1
* Vaginal buttonholing = 57
* Vascular injury = 11
* Neurological injury = 2

* Intraop graft complication y/n = 32
* Intraop graft complication gcc = 23
* Blood loss >500 ml = 108 - do this by grade
* Transfusion = 19
* Death = 1

* Return to theatre within 72 hours = 91
* Catheterisation for more than 10 days = 472 - do this by UDS
* Return to Hospital within 30 days - 88
* Thromboembolism = 4
```

Patient reported outcomes dependent on UDS

Section 18e: PGII vs UDS

```
tab GIIIncontinence PreOpUDSDes
```

Global Impression of Improvement for Incontinence	Pre-op Urodynamic diagnosis: USI	USI+voidi	Mixed	Mixed+voi	DOA	Normal voiding d	Total
0-Unanswered	4,866	147	1,065	41	33	144	4	6,300
1-Very much better	6,234	219	1,069	48	24	236	4	7,834
2-Much better	1,429	40	313	13	13	58	0	1,866
3-A little better	361	22	118	4	5	18	0	528
4-No change	174	8	71	4	3	10	0	270
5-A little worse	57	2	11	1	0	3	0	74
6-Much worse	46	3	18	1	2	2	0	72
7-Very much worse	28	4	4	0	0	0	0	36
Total	13,195	445	2,669	112	80	471	8	16,980

Section 18f: SUI vs UDS

```
tab ChangeinStressUrinaryIncontinum PreOpUDSDes
```

Change in Stress Urinary Incontinence	Pre-op Urodynamic diagnosis: USI	USI+voidi	Mixed	Mixed+voi	DOA	Normal	voiding d	Total
Cured	6,144	229	1,140	43	30	249	4	7,839
Improved	1,273	51	304	21	8	48	0	1,705
Never present	196	5	11	1	4	1	0	218
No change	193	11	59	4	2	9	0	278
Worse	42	5	10	0	1	1	0	59
Total	7,848	301	1,524	69	45	308	4	10,099

```
tab changesuiforlogreg PreOpUDSChi,
```

changesuif orlogreg	Pre-op Urodynamic diagnosis: USI	USI+vd	AnyDO	Total
0	7,418(97%)	279(95%)	1,546(95%)	9,243
1	236	15	76	327
Total	7,654	294	1,622	9,570

Section 18g: OAB vs UDS

```
tab ChangeinUrgencyUrgeIncontinum PreOpUDSDes
```

Change in Urgency / Urge Incontinence	Pre-op Urodynamic diagnosis: USI	USI+voidi	Mixed	Mixed+voi	DOA	Normal	voiding d	Total
Cured	1,167	57	297	13	4	37	1	1,576
Improved	1,651	75	511	19	14	38	0	2,308
Never present	2,970	82	200	12	10	140	2	3,416
New symptom	323	6	23	2	0	17	0	371
No change	1,035	44	342	21	11	42	1	1,496
Worse	413	20	121	1	7	18	0	580
Total	7,559	284	1,494	68	46	292	4	9,747

```
tab changeuuiforlogregns  PreOpUDSChi,
```

changeuuif orlogregns	Pre-op Urodynamic diagnosis: USI	USI+vd	AnyDO	Total
0	323 (4.3%)	6(2.1%)	25(1.5%)	354
1	7,238	276	1,583	9,097
Total	7,561	282	1,608	9,451

```
tab changeuuiforlogregwor   PreOpUDSChi,

changeuuif |
orlogregwo |   Pre-op Urodynamic diagnosis
         r |       USI     USI+vd      AnyDO       |     Total
-----------+---------------------------------------+----------
         0 |       413(5.8%)   20(7.6%)  129(8.7%) |       562
         1 |     7,148        262      1,479       |     8,889
-----------+---------------------------------------+----------
     Total |     7,561        282      1,608       |     9,451

          Pearson chi2(2) =  16.2218   Pr = 0.000

        tab changeuuiforlogregworactual         PreOpUDSChi, chi


changeuuif |
orlogregwo |   Pre-op Urodynamic diagnosis
   ractual |       USI     USI+vd      AnyDO |     Total
-----------+-------------------------------+----------
         0 |    413(9.7)  20(10)      129(2) |       562
         1 |     3,855        174      1,232 |     5,261
-----------+-------------------------------+----------
     Total |     4,268        194      1,361 |     5,823
Pearson chi2(2) =   0.1462   Pr = 0.930


tab changeuuiforlogregnswor    PreOpUDSChi,  chi

changeuuif |
orlogregns |   Pre-op Urodynamic diagnosis
       wor |       USI     USI+vd      AnyDO |     Total
-----------+-------------------------------+----------
         0 |       736         26        154 |       916
         1 |     6,825        256      1,454 |     8,535
-----------+-------------------------------+----------
     Total |     7,561        282      1,608 |     9,451

          Pearson chi2(2) =   0.1114   Pr = 0.946
```

Section 18h: Catheter vs UDS

```
* Catheterisation for more than 10 days by UDS

tab CatheterisationMoreThan10daysnum PreOpUDSDes

Catheterisa |
       tion |
   required |
   for more |
    than 10 |
       days |                          Pre-op Urodynamic diagnosis
    post-op |   USI  USI+voidi  Mixed  Mixed+voi  DOA    Normal  voiding d |     Total
------------+-----------------------------------------------------------------+----------
         No | 9,148    288      1,763    72       51        345          3 |    11,670
        Yes |  329     38         56      7        2         16          1 |       449
------------+-----------------------------------------------------------------+----------
      Total |  9,477   326     1,819     79       53        361          4 |    12,119


tab CatheterisationMoreThan10daysnum PreOpUDSChi, chi

Catheterisa |
       tion |
   required |
   for more |
    than 10 |
       days |   Pre-op Urodynamic diagnosis
    post-op |       USI             USI+vd             AnyDO |     Total
------------+---------------------------------------------+----------
         No |     9,148(97%)        288(88%)      1,886(97%) |    11,322
```

```
        Yes |       329                 38               65   |       432
------------+-----------------------------------------------------+----------
      Total |     9,477                 326            1,951 |    11,754

          Pearson chi2(2) =  60.7690   Pr = 0.000
```

```
tab CatheterisationMoreThan10daysnum PreOpUDSCathChi, chi
                Catheterisa |
       tion |
   required |
   for more |
    than 10 |   Pre-op Urodynamic
       days |       diagnosis
    post-op | Voiding d             No voidin  |     Total
------------+----------------------+----------
         No |       366             11,304     |    11,670
        Yes |        46 (11.1%)        403(3%) |       449
------------+----------------------+----------
      Total |       412             11,707     |    12,119

          Pearson chi2(1) =  66.5314   Pr = 0.000
```

BMI

Section 18i: PGII vs BMI

```
tab GIIIforlogreg BMIgrouped,
```

GIIIforlog reg	BMI 15-<18	18-<25	25-<30	30-<35	35-<40	40-<45	45-<50	50-<65	Total
0	3	1,748	2,549	1,526	626	147	39	11	6,649
1	3	160	239	223	105	37	15	4	786
Total	6	1,908	2,788	1,749	731	184	54	15	7,435

Section 18i2: Combined effect of BMI and age on PGII

```
table Agegrouped GIIInum BMIgrouped
```

Age at op	BMI and Global Impression of Improvement for Incontinence: 1 Better	1 No change	1 Worse	2 Better	2 No change	2 Worse	3 Better	3 No change	3 Worse	4 Better	4 No change	4 Worse	5 Better	5 No change	5 Worse
18-<50	2	2		992	66	14	1,163	64	15	687	82	18	291	30	7
50-<75	1	1		670	45	16	1,243	107	30	753	82	21	299	43	12
75-100				49	13	3	94	18	4	55	16	1	19	6	5

Age at op	BMI and Global Impression of Improvement for Incontinence: 6 Better	6 No change	6 Worse	7 Better	7 No change	7 Worse	8 Better	8 No change	8 Worse
18-<50	76	12		16	7	1	6	4	
50-<75	66	20	3	23	5	1	5		
75-100	2	1	1			1			

```
. table GradeforChi GIIInum BMIgrouped

*0 = consultant
```

Gradeforchi	BMI and Global Impression of Improvement for Incontinence: 1 Better	1 No change	1 Worse	2 Better	2 No change	2 Worse	3 Better	3 No change	3 Worse	4 Better	4 No change	4 Worse	5 Better	5 No change	5 Worse	6 Better	6 No change	6 Worse
0	2	2		1,377	102	23	2,003	142	41	1,166	154	22	480	65	16	121	30	4
1	1	1		317	22	8	460	38	7	315	22	14	130	15	6	24	1	

Gradeforchi	BMI and Global Impression of Improvement for Incontinence: 7 Better	7 No change	7 Worse	8 Better	8 No change	8 Worse
0	34	10	3	9	4	
1	5	1		1		

Section 18j: Bladder injury by grade of operator by BMI

```
. table BMIgrouped IntraopBladderinjurynum GradeforChi
```

GradeforChi and Intra-op-Bladder injury

BMI	0 Unanswered	0 No	0 Yes	1 Unanswered	1 No	1 Yes
15-<18		10			2	
18-<25	4	2,218	76	1	488	55
25-<30	9	3,301	66	3	775	85
30-<35	9	2,095	31	4	563	24
35-<40	2	902	11		242	4
40-<45	1	266	6		52	
45-<50		76	1		11	2
50-<65		20	1		2	

Section 18k: Catheter by BMI

```
tab CatheterisationMoreThan10daysnum BMIgrouped
```

Catheterisation required for more than 10 days

post-op	BMI 15-<18	18-<25	25-<30	30-<35	35-<40	40-<45	45-<50	50-<65	Total
No	7	2,064	2,994	1,916	813	204	63	16	8,077
Yes	0	84	143	60	19	6	0	0	312
Total	7	2,148	3,137	1,976	832	210	63	16	8,389

****

*BMI ********

****

```
. table onlyUDSUSI GIIInum BMIgrouped
```

onlyUDSUSI	BMI and Global Impression of Improvement for Incontinence: 1 Better	1 No change	1 Worse	2 Better	2 No change	2 Worse	3 Better	3 No change	3 Worse	4 Better	4 No change	4 Worse	5 Better	5 No change	5 Worse	6 Better	6 No change	6 Worse	8 Better	8 No change	8 Worse
1	1		1,363	87	25	1,976	118	30	1,126	118	28	666	68	22	108	19	2	28	8	1	7	2	

Grade of operator

Section 18l: PGII vs Grade

```
tab GradeforChi GIIInum, chi
```

```
           | Global Impression of Improvement
GradeforCh |         for Incontinence
         i |    Better  No change      Worse |     Total
-----------+---------------------------------+----------
         0 |     8,149        669        135 |     8,953
         1 |     1,880        141         43 |     2,064
-----------+---------------------------------+----------
     Total |    10,029        810        178 |    11,017

          Pearson chi2(2) =   4.3759   Pr = 0.112
```

Section 18m: SUI vs Grade

```
tab GradeforChi changesuiforlogreg, chi
```

```
GradeforCh |  changesuiforlogreg
         i |         0          1 |     Total
-----------+----------------------+----------
         0 |     7,908        266 |     8,174
         1 |     1,885         68 |     1,953
-----------+----------------------+----------
     Total |     9,793        334 |    10,127

          Pearson chi2(1) =   0.2560   Pr = 0.613
```

```
* Bladder injury = 639
```

Section 18n: Bladder injury vs grade

```
tab GradeforChi IntraopBladderinjuryforlogreg, chi
```

```
           | IntraopBladderinjuryf
GradeforCh |       orlogreg
         i |         0          1 |     Total
-----------+----------------------+----------
         0 |       313     13,843 |    14,156
         1 |       290      3,399 |     3,689
-----------+----------------------+----------
     Total |       603     17,242 |    17,845

          Pearson chi2(1) = 286.1397   Pr = 0.000
```

Section 18o: Return to theatre vs grade

```
* Return to theatre within 72 hours = 91      RTTReturntotheatreforprocednum

tab GradeforChi RTTReturntotheatreforprocednum, chi
```

```
           | RTT Return to theatre
           | for procedure-related
GradeforCh |  event within 72 hrs
         i |        No        Yes |     Total
-----------+----------------------+----------
         0 |    10,202         53 |    10,255
         1 |     2,311         31 |     2,342
-----------+----------------------+----------
     Total |    12,513         84 |    12,597

          Pearson chi2(1) =  18.7377   Pr = 0.000
```

```
           | RTT Return to theatre
           | for procedure-related
GradeforCh |  event within 72 hrs
         i |        No              Yes |     Total
-----------+----------------------------+----------
         0 |    10,202         53(0.5%) |    10,255
         1 |     2,311         31(1.3%) |     2,342
```

```
-----------+----------------------------+----------
     Total |    12,513                84 |    12,597

          Pearson chi2(1) =  18.7377   Pr = 0.000
****Interesting to look at what the RTT was for - only 84 - look at manually
```

Section 18p: Catheter vs grade

```
* Catheterisation for more than 10 days = 472 CatheterisationMoreThan10daysnum

tab GradeforChi CatheterisationMoreThan10daysnum, chi

           |    Catheterisation
           |   required for more
GradeforCh | than 10 days post-op
         i |        No        Yes |     Total
-----------+----------------------+----------
         0 |     9,885        347 |    10,232
         1 |     2,227        106 |     2,333
-----------+----------------------+----------
     Total |    12,112        453 |    12,565

          Pearson chi2(1) =   7.2572   Pr = 0.007
```

Section 18q: Return to Hosptial vs grade

```
* Return to Hospital within 30 days = 88        RTHReturntohospital30numlogreg

tab GradeforChi RTHReturntohospital30numlogreg, chi

           | RTHReturntohospital30
GradeforCh |       numlogreg
         i |         0                1 |     Total
-----------+----------------------------+----------
         0 |       788         74(8.6%) |       862
         1 |       145          5(3.3%) |       150
-----------+----------------------------+----------
     Total |       933               79 |     1,012

          Pearson chi2(1) =   4.8957   Pr = 0.027
```

Bladder injury

Section 18r: PGII vs Bladder injury

```
*1. Global Impression of Incontinence
*Improved (VMB&MB)  vs   No change (LB/NoCh)  vs  Worse (LW/MW/VMW)  -  Chi

tab GIInum IntraopBladderinjuryforlogreg,

Global Impression | IntraopBladderinjuryf
   of Improvement |       orlogreg
 for Incontinence |         0          1 |     Total
------------------+----------------------+----------
          Better |       297      9,892 |    10,189
       No change |        31        797 |       828
           Worse |         5        182 |       187
------------------+----------------------+----------
           Total |       333     10,871 |    11,204



*VMB/MB vs the others
tab GIIIforlogreg IntraopBladderinjuryforlogreg, chi

           | IntraopBladderinjuryf
GIIIforlog |       orlogreg
       reg |         0          1 |     Total
-----------+----------------------+----------
         0 |       297      9,892 |    10,189
         1 |        36        979 |     1,015
-----------+----------------------+----------
     Total |       333     10,871 |    11,204

          Pearson chi2(1) =   1.2780   Pr = 0.258
```

Section 18s: SUI vs bladder injury

```
*2. Change in Stress Urinary Incontinence
*Cured/Improved     vs      No change/Worse

tab changesuiforlogreg IntraopBladderinjuryforlogreg, chi

           | IntraopBladderinjuryf
changesuif |       orlogreg
  orlogreg |         0          1 |     Total
-----------+----------------------+----------
         0 |       292      9,760 |    10,052
         1 |        19        330 |       349
-----------+----------------------+----------
     Total |       311     10,090 |    10,401

          Pearson chi2(1) =   7.4973   Pr = 0.006


*I have removed "never present" - comment in text
```

Section 18t: OAB vs blader injury

```
*3. Change in Urgency Urge Incontinence
*a. New
tab changeuuiforlogregns IntraopBladderinjuryforlogreg, chi

           | IntraopBladderinjuryf
changeuuif |       orlogreg
orlogregns |         0          1 |     Total
-----------+----------------------+----------
         0 |        13        382 |       395
         1 |       288      9,563 |     9,851
-----------+----------------------+----------
     Total |       301      9,945 |    10,246

          Pearson chi2(1) =   0.1800   Pr = 0.671

*b. Worse

tab changeuuiforlogregwor IntraopBladderinjuryforlogreg, chi

changeuuif | IntraopBladderinjuryf
```

```
orlogregwo |       orlogreg
         r |         0          1 |     Total
-----------+----------------------+----------
         0 |        18        586 |       604
         1 |       283      9,359 |     9,642
-----------+----------------------+----------
     Total |       301      9,945 |    10,246

          Pearson chi2(1) =   0.0040   Pr = 0.949


*c. New and worse
*
tab changeuuiforlogregnswor IntraopBladderinjuryforlogreg, chi


changeuuif | IntraopBladderinjuryf
orlogregns |       orlogreg
       wor |         0          1 |     Total
-----------+----------------------+----------
         0 |        31        968 |       999
         1 |       270      8,977 |     9,247
-----------+----------------------+----------
     Total |       301      9,945 |    10,246

          Pearson chi2(1) =   0.1062   Pr = 0.745
```

Section 18u: RTT vs bladder injury

```
* Return to theatre within 72 hours = 91

tab RTTReturntotheatreforprocednum IntraopBladderinjuryforlogreg, chi
 RTT Return |
 to theatre |
        for |
procedure-r |
     elated |
      event | IntraopBladderinjuryf
  within 72 |       orlogreg
        hrs |         0          1 |     Total
------------+----------------------+----------
         No |       368     12,367 |    12,735
        Yes |    7(1.9%)   83(0.7%)|        90
------------+----------------------+----------
      Total |       375     12,450 |    12,825

          Pearson chi2(1) =   7.5228   Pr = 0.006
```

Section 18v: Catheter vs bladder injury

```
* Catheterisation for more than 10 days = 472

tab CatheterisationMoreThan10daysnum IntraopBladderinjuryforlogreg, chi
Catheterisa |
       tion |
   required |
   for more |
    than 10 | IntraopBladderinjuryf
       days |       orlogreg
    post-op |         0          1 |     Total
------------+----------------------+----------
         No |       349     11,972 |    12,321
        Yes |        26        443 |       469
------------+----------------------+----------
      Total |       375     12,415 |    12,790

          Pearson chi2(1) =  11.6686   Pr = 0.001
```

Section 18w: RTH vs bladder injury

```
* Return to Hospital within 30 days - 88
tab RTHReturntohospital30numlogreg IntraopBladderinjuryforlogreg, chi
RTHReturnt | IntraopBladderinjuryf
ohospital3 |       orlogreg
0numlogreg |         0          1 |     Total
-----------+----------------------+----------
```

```
          0 |         23         948 |         971
          1 |          4          83 |          87
------------+----------------------+-----------
      Total |         27       1,031 |       1,058

           Pearson chi2(1) =   1.5952   Pr = 0.207
```

****

Section 19: Set up for logistic regression

```
*LOGISTIC REGRESSION
* for logistic regression
* question - do things have to be significant to put them in the log reg?
* for logistic regression - need the variables to be in the 0 or 1 - so need
*to look at GIIIforlogreg - to work out how to do this - need to redo them and
*rename them "logreg"
* put an "i." if it is binary but if the data is continuous then no need for
*the i

*include centre

**logistic GIIIforlogreg
*Ageatop
*PelvicfloorexerciseforChi
*PreOpUDSChi - I really want this to be 3 options - can I do that?
*GradeforChi
*IntraopBladderinjurynum
*BMI   *****ERROR******BMI:  factor variables may not contain noninteger values

*********NEED TO ADD IN TIME FROM OPERATION FOLLOW UP*********

i.followup6weeks i.followup3months i.followup6months i.followup12months


*LOGISTIC REG
logistic GIIIforlogreg Ageatop i.PelvicfloorexerciseforChi i.PreOpUDSChiUSI i.PreOpUDSChiAnyDO i.GradeforChi i.IntraopBladderinjuryforlogreg BMIcorrect

note: 1.followup12months omitted because of collinearity

Logistic regression                                             Number of obs     =      6,036
                                                                LR chi2(10)       =     172.53
                                                                Prob > chi2       =     0.0000
Log likelihood = -1986.4984                                     Pseudo R2         =     0.0416

------------------------------------------------------------------------------
             GIIIforlogreg | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
---------------------------+--------------------------------------------------------------------
                   Ageatop |   1.018688   .0035805     5.27   0.000     1.011695     1.02573
1.PelvicfloorexerciseforChi |   1.242735   .1450959     1.86   0.063     .9885447    1.562287
          1.PreOpUDSChiUSI |   1.612789   .3533802     2.18   0.029     1.049711     2.47791
       1.PreOpUDSChiAnyDO |   .7600753   .1748938    -1.19   0.233     .4841665    1.193215
            1.GradeforChi |   .8798129   .0964035    -1.17   0.243      .709777    1.090583
1.IntraopBladderinjuryforlogreg |   .7590465   .1762647    -1.19   0.235      .481508    1.196557
                BMIcorrect |   1.049964    .007608     6.73   0.000     1.035158    1.064981
                     _cons |   .0032772   .0018189   -10.31   0.000     .0011043    .0097257
------------------------------------------------------------------------------
```

Appendix 4: Additional results for pilot analysis (Chapter 2)

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Patient characteristics

	RPT		PUB	
Age	Number	%	Number	%
18-<30	138	0.8	50	3.8
30-<40	1982	10.9	145	10.9
40-<50	6530	35.8	206	15.5
50-<60	4867	26.7	240	18.0
60-<70	2924	16.0	235	17.7
70-<80	1480	8.1	288	21.7
80+	308	1.7	166	12.5
Total	**18229**		**1330**	
Not recorded/nonsense	534		56	

Table 1: Range of age for patients receiving RPT and PUB pilot analysis

	RPT		PUB	
BMI	Number	%	Number	%
15-<18	14	0.1	2	0.3%
18-<25	2,943	24.8	160	21.5%
25-<30	4,401	37.1	242	32.6%
30-<35	2,838	23.9	177	23.8%
35-<40	1,209	10.2	103	13.9%
40-<45	338	2.9	47	6.3%
45-<50	92	0.8	9	1.2%
50-<65	24	0.2	3	0.4%
Total	**11858**		**743**	
Not recorded or nonsense	6904		643	

Table 2: Range of BMI for patients receiving RPT and PUB pilot analysis

	RPT		PUB	
PFMT	Number	%	Total	%
Offered and accepted	14535	88.1%	929	82.1
Offered and declined	550	3.3%	34	3.0
Not offered	1425	8.6%	168	14.9
Total	16510		1131	
Unanswered	2253		255	

Table 3: Use of pelvic floor muscle training prior to RPT and PUB in pilot analysis

	RPT		PUB	
Urodynamics	Number	%	Number	%
Reported as done with result recorded	16404	92.7	1153	92.0
Reported done but no result recorded	693	3.9	41	3.3
Reported as not done	601	3.4	59	4.7
Total	**17698**		**1253**	
Unanswered if had done	1065		133	

Table 4: Record of whether urodynamics were performed for RPT and PUB in pilot analysis

	RPT		PUB	
Pre-operative urodynamic diagnosis	Number	%	Number	%
USI	12655	77.2	773	67.0
USI, Voiding dysfunction	418	2.5	56	4.9
Occult USI	111	0.7	9	0.7
Normal	454	2.8	46	4.0
Mixed	2562	15.6	250	21.7
Mixed + Voiding dysfunction	105	0.6	10	0.8
DOA	73	0.5	4	0.4
USI + Overflow/chronic retention	7	0.04	3	0.3
Voiding dysfunction	7	0.04	2	0.2
DOA + voiding dysfunction	6	0.04	0	0.0
Mixed + overflow/chronic retention	4	0.02	0	0.0
Overflow/chronic retention	1	0.01	0	0.0
Fistula	1	0.01	0	0.0
Total	**16404**		**1153**	
Urodynamics not performed	601		59	
Unanswered	1758		174	

Table 5: Pre-operative Urodynamic diagnosis recorded for RPT and PUB in the pilot analysis

Previous surgery prior to PUB	Frequency
RPT/TVT-A	168
PUB	165
TOT/TVT-O/ TOT-Needleless	122
Colposuspension open	74
Single Incision tape/mini sling	12
Anterior repair (AR) + BNB	11
Stamey Procedure	11
AFS	10
MMK	6
Unrecorded	84

Table 6: SUI procedures performed prior to this PUB in pilot analysis

Operative characteristics and intraoperative complications

	RPT		PUB	
Anaesthetic	Number	%	Number	%
General anaesthetic	12945	70.2	882	65.2
Spinal	2412	13.1	36	2.7
Local anaesthetic	74	0.4	336	24.8
Local anaesthetic + sedation	2526	13.7	84	6.2
General anaesthetic + Spinal	79	0.4	2	0.1
General anaesthetic + Epidural	54	0.3	0	0.0
General anaesthetic + Caudal	343	1.9	13	1.0
Caudal	5	0.0	0	0.0
Total	**18438**		**1353**	
Unanswered	325		33	

Table 7: Anaesthetic used for RPT and PUB in pilot analysis

	RPT		PUB	
Grade of operator	Number	%	Number	%
Consultants	14334	77.5	1160	85.6
Associate Specialists	64	0.3	4	0.3
Subspecialty Trainees	1147	6.2	83	6.1
Specialty Trainees	2556	13.8	86	6.3
Staff Grades	202	1.1	19	1.4
FTSTA	7	0.0	0	0.0
Other	189	1.1	4	0.3
Total	**18499**		**1356**	
Unanswered	264		30	

Table 8: Grade of operator for RPT and PUB in pilot analysis (Fixed Term Specialty Training Appointments (FTSTA))

Bladder perforation with RPT

Bladder perforation	Number
Yes	639
No	17855
Total	**18763**
Unanswered	269

Table 9: Bladder perforation during RPT in pilot analysis

% Perforation	Different rates depending on exclusions
3.46%	If unanswered are excluded
3.41%	If unanswered are included as not perforated
4.84%	If unanswered are included as all perforated

Table 10: Different rates of bladder perforation depending on exclusions in pilot analysis

Complication with RPT	%	Yes	No	Total	Unanswered
Blood loss > 500ml	0.40	50	12470	12520	169
Vaginal Button-holing	0.54	42	7753	7795	4894
Peri-op blood transfusion	0.06	7	12512	12519	170
Urethral injury	0.14	11	7783	7794	4895
Vascular injury	0.05	6	12513	12519	170
Peri-op VTE	0.03	3	10992	10995	1694
Neuro-logical injury	0.01	1	12517	12518	171
Bowel injury	0.01	1	12517	12518	171
Death	0.01	1	10993	10994	1695
Ureteric injury	0.00	0	12520	12520	169

Table 11: Complications of RPT with no concomitant surgery (n=12689) in pilot analysis

Patient Reported Outcomes: PGII: RPT and PUB

	RPT		All PUB		First PUB		Repeat PUB	
PGII	Number	%	N	%	N	%	N	%
Very much better	8349	73.5	249	33.6	140	32.9	97	33.7
Much better	1990	17.5	190	25.6	115	27.1	68	23.6
A little better	553	4.9	132	17.8	74	17.4	53	18.5
No change	285	2.5	147	19.7	85	20.1	58	20.1
A little worse	74	0.6	16	2.2	7	1.6	9	3.1
Much worse	78	0.7	5	0.7	4	0.9	1	0.3
Very much worse	37	0.3	3	0.4	0	0.0	2	0.7
Total	**11366**		**742**		**425**		**288**	
Unanswered	7397		644					

Table 12: Patient Reported Global Impression of Improvement of Incontinence (PGII) following RPT and PUB in pilot analysis

	RPT		All PUB	
PGII (grouped)	Number	%	Number	%
Better (VMB&MB)	10339	91.0	439	59.2%
No change (LB&NC)	838	7.4	279	37.5%
Worse (LW,MW&VMW)	189	1.6	24	3.3%

Table 13: PGII grouped for RPT and PUB in pilot analysis

PGII	PUB	RPT	Marg na Row Tota s
VMB+MB	439 (660.5) [74.28]	10339 (10117.5) [4.85]	10778
Other	303 (81.5) [601.93]	1027 (1248.5) [39.3]	1330
Marg na Co umn Tota s	742	11366	12108 (Grand Tota)
The chi-square statistic is 720.3516. The p-value is <0.01. This result is significant at p < .05.			

Table 14: Chi^2 test to compare PGII for RPT and PUB in pilot analysis.

Patient reported outcomes: SUI: RPT and PUB

	RPT		All PUB		First PUB		Repeat PUB	
Change in SUI	Number	%	N	%	N	%	N	%
Cured	8288	77.6	189	28.5	105	27.6	76	29.7
Improved	1808	16.9	304	45.8	185	48.7	108	42.2
No change	288	2.7	154	23.2	83	21.9	62	24.2
Worse	62	0.6	12	1.8	5	1.3	7	2.7
Never present	239	2.2	5	0.7	2	0.5	3	1.2
New symptom	0	0.0	0	0.0	0	0.0	0	0
Total	10685		664		380		256	
Unanswered	8078		722					

Table 15: Patient reported Change in Stress Urinary Incontinence (SUI) following RPT and PUB in pilot analysis

SUI	RPT	PUB	Row Tota s
Cured + mproved	10096 (9969.47) [1.61]	493 (619.53) [25.84]	10589
Not cured + mproved	589 (715.53) [22.38]	171 (44.47) [360.08]	760
Co umn Tota s	10685	664	11349 (Grand Tota)
The ch -square stat st c s 409.9009. The *p*-va ue s < .00001. The resu t s s gn f cant at *p* < .05.			

Table 16: Chi^2 test to compare Change in SUI cured + improved vs not cured + improved for RPT vs PUB in the pilot analysis

SUI	RPT	PUB	Marg na Row Tota s
Cured	8288 (7981.03) [11.81]	189 (495.97) [189.99]	8477
Not cured	2397 (2703.97) [34.85]	475 (168.03) [560.77]	2872
Marg na Co umn Tota s	10685	664	11349 (Grand Tota)
The ch -square stat st c s 797.419. The p-va ue s <0.01. Th s resu t s s gn f cant at p < .05.			

Table 17: Chi2 test to compare Change in SUI Cured vs not cured for RPT vs PUB in the pilot analysis

Patient reported outcomes: OAB: RPT and PUB

	RPT		All PUB	
Change in OAB	Number	%	Number	%
Cured	1635	15.9	31	5.0
Improved	2408	23.4	129	20.7
No change	1573	15.3	229	36.8
Worse	608	5.9	24	3.9
Never present	3670	35.7	205	32.8
New symptom	396	3.8	5	0.8
Total	10290		623	
Unanswered	8473		763	

Table 18: Patient reported change in Overactive Bladder Symptoms (OAB) following RPT and PUB in pilot analysis

	RPT		All PUB	
Change in OAB	Number	%	Number	%
Cured	1635	26.3	31	7.5
Improved	2408	38.7	129	31.2
No change	1573	25.3	229	55.5
Worse	608	9.7	24	5.8
Total	6224		413	

Table 19: Patient reported change in OAB in patients with *pre-operative OAB following RPT and PUB in pilot analysis*

	RPT		All PUB	
Change in OAB	Number	%	Number	%
New symptom	396	9.7	5	2.4
Never present	3670	90.3	205	97.6
Total	4066		210	

Table 20: Patient reported change in OAB in patients without *pre-operative OAB following RPT and PUB in pilot analysis*

OAB	RPT	PUB	*Row Totals*
New OAB	396 (381.31) [0.57]	5 (19.69) [10.96]	401
Never present	3670 (3684.69) [0.06]	205 (190.31) [1.13]	3875
Column Totals	4066	210	4276 (Grand Tota)
The ch -square stat st c s 12.7224. The *p*-va ue s .000361. The resu t s s gn f cant at *p* <			

Table 21: Chi^2 test to compare rates of patient reported new OAB betwen RPT and PUB in the pilot analysis

Post operative complications: RPT and PUB

Patients used for this had no concomitant surgery.
RPT n=12689 (4355 concomitant surgery, 1719 missing data)
PUB n=973 (83 concomitant surgery, 330 missing data)

	RPT			PUB			p-value
	Number	%	Missing	Number	%	Missing	
Return to Theatre <72 hours	53/8729	0.6	3960	1/574	0.2	399	ns
Return to hospital <30 days	58/719	8.1	11970	5/183	2.7	790	0.01
Readmitted to hospital <30 days	368/8560	4.3	4129	5/552	0.9	421	<0.01

Table 22: Return to theatre, return to hospital and readmitted to hospital following RPT and PUB in pilot analysis

Return to theatre <72 hr	**PUB**	**RPT**	Marg na Row Tota s
Yes	1 (3.33) [1.63]	53 (50.67) [0.11]	54
No	573 (570.67) [0.01]	8676 (8678.33) [0]	9249
Marg na Co umn Tota s	574	8729	9303 (Grand Tota)
The ch -square stat st c s 1.7494. The p-va ue s .185948. Th s resu t s not s gn f cant at p < .05			

Table 23: Chi² test to compare return to theatre following RPT and PUB in pilot analysis

Return to hosp ta w th n 30 days for procedure re ated event	**PUB**	**RPT**	Marg na Row Tota s
Yes	5 (12.78) [4.74]	58 (50.22) [1.21]	63
No	178 (170.22) [0.36]	661 (668.78) [0.09]	839
Marg na Co umn Tota s	183	719	902 (Grand Tota)
The ch -square stat st c s 6.3896. The p-va ue s .011479. Th s resu t s s gn f cant at p < .05.			

Table 24: Chi² test to compare return to hospital following RPT and PUB in pilot analysis

Readm tted to hosp ta w th n 30 days for procedure re ated event	**PUB**	**RPT**	Marg na Row Tota s
Yes	5 (22.6) [13.7]	368 (350.4) [0.88]	373
No	547 (529.4) [0.58]	8192 (8209.6) [0.04]	8739
Marg na Co umn Tota s	552	8560	9112 (Grand Tota)
The ch -square stat st c s 15.2087. The p-va ue s .000096. Th s resu t s s gn f cant at p < .05.			

Table 25: Chi² test to compare readmission to hospital following RPT and PUB in pilot analysis

Impact of patient characteristics on outcomes
Age and Patient Reported Outcomes: RPT

Age	19-29		30-39		40-49		50-59		60-69		70-79		80+	
PGII grouped	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Better (VMB&MB)	73	89.0	1031	91.6	3648	92.6	2673	91.9	1649	89.2	804	85.4	130	73.9
No change (LB&NC)	8	9.8	79	7.0	245	6.2	191	6.6	158	8.5	109	11.6	34	19.3
Worse (LW, MW, VMW)	1	1.2	16	1.4	45	1.1	46	1.6	41	2.2	28	3.0	12	6.8
Tota	82		1126		3938		2910		1848		941		176	

Table 26: PGII grouped, split by age for RPT in pilot analysis

Age	19-29		30-39		40-49		50-59		60-69		70-79		80+	
SUI	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Cured	56	75.7	843	78.9	3001	80.1	2193	79.2	1304	74.2	636	71.1	90	54.5
Improved	14	18.9	177	16.6	576	15.4	450	16.2	320	18.2	194	21.7	49	29.7
No change	2	2.7	24	2.2	73	1.9	69	2.5	69	3.9	29	3.2	17	10.3
Worse	1	1.4	3	0.3	16	0.4	11	0.4	12	0.7	15	1.7	4	2.4
New symptom	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Never Present	1	1.4	21	2.0	80	2.1	47	1.7	52	3.0	21	2.3	5	3.0
Tota	74		1068		3746		2770		1757		895		165	

Table 27: Change in SUI, split by age for RPT in pilot analysis

Age: OAB with pre-op symptom	19-29		30-39		40-49		50-59		60-69		70-79		80+	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Cured	8	18.6	160	27.2	565	28.0	437	26.9	281	25.7	136	22.0	20	16.5
Improved	17	39.5	219	37.2	751	37.2	649	39.9	442	40.4	241	39.1	47	38.8
No change	12	27.9	147	25.0	508	25.2	395	24.3	264	24.2	172	27.9	35	28.9
Worse	6	14.0	63	10.7	195	9.7	144	8.9	106	9.7	68	11.0	19	15.7
Tota	43		589		2019		1625		1093		617		121	

Table 28: Change in OAB for patients with *pre-operative OAB, split by age for RPT in pilot analysis*

Age: OAB without pre-op symptom	19-29		30-39		40-49		50-59		60-69		70-79		80+	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
New symptom	1	4.3	30	6.7	155	9.7	99	9.5	72	11.9	31	12.7	4	10.8
Never Present	22	95.7	415	93.3	1440	90.3	938	90.5	533	88.1	213	87.3	33	89.2
Tota	23		445		1595		1037		605		244		37	

Table 29: Change in OAB for patients without *pre-operative OAB, split by age for RPT in pilot analysis*

Impact of patient characteristics on outcomes
Age and Patient Reported Outcomes: PUB

Age	19-29		30-39		40-49		50-59		60-69		70-79		80+	
PGII grouped	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Better (VMB&MB)	17	58.6	41	53.2	66	57.9	66	53.2	87	67.4	94	58.8	53	63.1
No change (LB&NC)	12	41.4	34	44.2	45	39.5	55	44.4	39	30.2	58	36.3	27	32.1
Worse (LW, MW, VMW)	0	0.0	2	2.6	3	2.6	3	2.4	3	2.3	8	5.0	4	4.8
Tota	29		77		114		124		129		160		84	

Table 30: PGII grouped, split by age for PUB in pilot analysis

Age	19-29		30-39		40-49		50-59		60-69		70-79		80+	
SUI	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Cured	7	25.0	13	17.6	27	27.3	38	32.8	31	28.4	40	28.4	27	34.6
Improved	14	50.0	38	51.4	44	44.4	53	45.7	59	54.1	59	41.8	30	38.5
No change	7	25.0	20	27.0	26	26.3	22	19.0	18	16.5	34	24.1	21	26.9
Worse	0	0.0	2	2.7	1	1.0	2	1.7	1	0.9	6	4.3	0	0.0
New symptom	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Never Present	0	0.0	1	1.4	1	1.0	1	0.9	0	0.0	2	1.4	0	0.0
Tota	28		74		99		116		109		141		78	

Table 31: Change in SUI, split by age for PUB in pilot analysis

Age: OAB with pre-op symptom	19-29		30-39		40-49		50-59		60-69		70-79		80+	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Cured	1	5.6	3	10.3	2	4.3	5	6.3	7	9.6	9	8.5	3	6.1
Improved	10	55.6	5	17.2	18	39.1	24	30.4	23	31.5	33	31.1	14	28.6
No change	6	33.3	16	55.2	26	56.5	46	58.2	38	52.1	58	54.7	30	61.2
Worse	1	5.6	5	17.2	0	0.0	4	5.1	5	6.8	6	5.7	2	4.1
Tota	18		29		46		79		73		106		49	

Table 32: Change in OAB for patients with pre-operative OAB, split by age for PUB in pilot analysis

Age: OAB without pre-op symptom	19-29		30-39		40-49		50-59		60-69		70-79		80+	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%
New symptom	0	0	0	0	1	2.3	1	3.0	1	3.2	0	0	2	9.5
Never Present	10	100	37	100	42	97.7	32	97.0	30	96.8	32	100	19	90.5
Tota	10		37		43		33		31		32		21	

Table 33: Change in OAB for patients without pre-operative OAB, split by age for PUB in pilot analysis

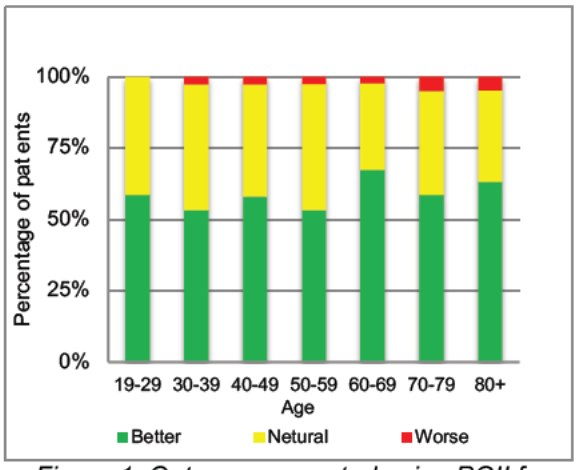


Figure 1: Outcomes reported using PGII for patients undergoing PUB, in the BSUG database by age

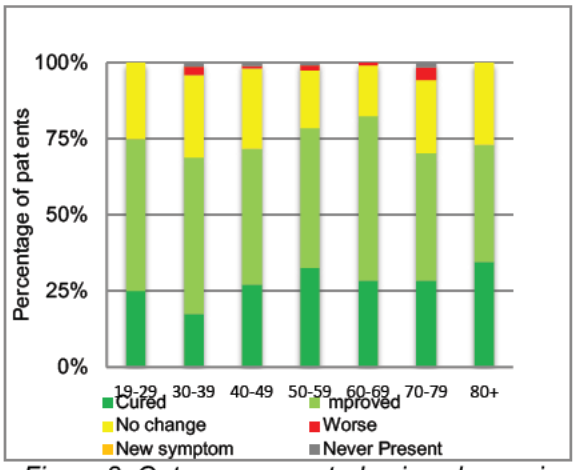


Figure 2: Outcomes reported using change in SUI for patients undergoing PUB, in the BSUG database by age

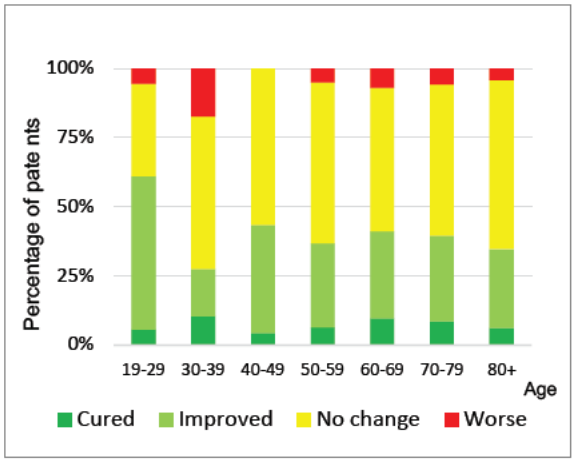


Figure 3: Outcomes reported using change in OAB for patients with pre-existing OAB undergoing PUB, in the BSUG database, by age

Impact of BMI at operation on other patient characteristics

BMI	18-<25	25-<30	30-<35	35-<40	40-<45	45-<50	50-65
Age at operat on (11,596)							
18-<50	1,648 57%	2,075 48%	1,306 47%	589 50%	159 48%	41 45%	13 54%
50-<75	1,137 39%	2,045 47%	1,345 49%	553 47%	163 49%	49 53%	10 42%
75-100	103 4%	191 4%	119 4%	39 3%	8 2%	2 2%	1 4%
Tota	2,888	4,311	2,770	1,181	330	92	24

Table 34: Age at operation by BMI category for RPT in pilot analysis

BMI	18-<25	25-<30	30-<35	35-<40	40-<45	45-<50	50-65
Pre-op Urodynam c d agnos s (10,982)							
USI	2,245 82.1%	3,263 80.1%	2,021 76.8%	825 73.8%	230 73.0%	62 72.1%	15 65.2%
USI + vo d ng dysfunct on	63 2.3%	106 2.6%	69 2.6%	30 2.7%	6 1.9%	4 4.7%	2 8.7%
M xed	292 10.7%	547 13.4%	438 16.6%	235 21.0%	70 22.2%	18 20.9%	5 21.7%
M xed + vo d ng dysfunct on	10 0.4%	14 0.3%	19 0.7%	5 0.4%	4 1.3%	0 0.0%	1 4.3%
DOA	11 0.4%	22 0.5%	13 0.5%	7 0.6%	1 0.3%	1 1.2%	0 0.0%
Norma	111 4.1%	118 2.9%	70 2.7%	16 1.4%	4 1.3%	1 1.2%	0 0.0%
Vo d ng dysfunct on	2 0.1%	3 0.1%	3 0.1%	0 0.0%	0 0.0%	0 0.0%	0 0.0%
Tota	2,734	4,073	2,633	1,118	315	86	23

Table 35: UDS diagnosis by BMI category for RPT in pilot analysis

Tables to assess whether BMI at operation is linked to the finding of mixed UDS result

BMI	18-<25	25-<30	30-<35	35-<40	40-<45	45-<50	50-65
Pre-op Urodynam c d agnos s (10,982)							
M xed	292 10.7%	547 13.4%	438 16.6%	235 21.0%	70 22.2%	18 20.9%	5 21.7%
Tota	2,734	4,073	2,633	1,118	315	86	23

Table 36: percentage of mixed UDS by BMI category for RPT in pilot analysis

	18-25	25-<30	*Row Totals*
M xed	292 (336.98) [6.00]	547 (502.02) [4.03]	839
Not m xed	2442 (2397.02) [0.84]	3526 (3570.98) [0.57]	5968
Column Totals	2734	4073	6807 (Grand Tota)
The ch -square stat st c s 11.4449. The *p*-va ue s .000717. The resu t s s gn f cant at $p < .05$			

Table 37: Chi² test to assess difference in Mixed urodynamics with BMI in pilot analysis

	18-25	30-<35	*Row Totals*
M xed	292 (371.94) [17.18]	438 (358.06) [17.85]	730
Not m xed	2442 (2362.06) [2.71]	2194 (2273.94) [2.81]	4636
Column Totals	2734	2632	5366 (Grand Tota)
The ch -square stat st c s 40.5424. The *p*-va ue s < .00001. The resu t s s gn f cant at $p < .05$.			

Table 38: Chi² test to assess difference in Mixed urodynamics with BMI in pilot analysis

	18-25	35-<40	*Row Totals*
M xed	292 (374.04) [18.00]	235 (152.96) [44.01]	527
Not m xed	2442 (2359.96) [2.85]	883 (965.04) [6.98]	3325
Column Totals	2734	1118	3852 (Grand Tota)
The ch -square stat st c s 71.8309. The *p*-va ue s < .00001. The resu t s s gn f cant at $p < .05$.			

Table 39: Chi² test to assess difference in Mixed urodynamics with BMI in pilot analysis

	18-25	40-<45	*Row Totals*
M xed	292 (324.60) [3.27]	70 (37.40) [28.42]	362
Not m xed	2442 (2409.40) [0.44]	245 (277.60) [3.83]	2687
Column Totals	2734	315	3049 (Grand Tota)
The ch -square stat st c s 35.9621. The *p*-va ue s < .00001. The resu t s s gn f cant at $p < .05$.			

Table 40: Chi² test to assess difference in Mixed urodynamics with BMI in pilot analysis

	18-25	45-<50	*Row Totals*
M xed	292 (300.55) [0.24]	18 (9.45) [7.73]	310
Not m xed	2442 (2433.45) [0.03]	68 (76.55) [0.95]	2510
Column Totals	2734	86	2820 (Grand Tota)
The ch -square stat st c s 8.9526. The *p*-va ue s .002771. The resu t s s gn f cant at $p < .05$.			

Table 41: Chi² test to assess difference in Mixed urodynamics with BMI in pilot analysis

	18-25	50-<65	*Row Totals*
M xed	292 (294.52) [0.02]	5 (2.48) [2.57]	297
Not m xed	2442 (2439.48) [0.00]	18 (20.52) [0.31]	2460
Column Totals	2734	23	2757 (Grand Tota)
The ch -square stat st c s 2.9019. The *p*-va ue s .088473. The resu t s *not* s gn f cant at $p < .05$.			

Table 42: Chi² test to assess difference in Mixed urodynamics with BMI in pilot analysis

Table to demonstrate OAB symptoms by BMI category to show the percentage of pre-operative OAB symptoms are higher with higher BMI

	BMI	18-<25	25-<30	30-<35	35-<40	40-<45	45-<50
Pre-op OAB	Cured	234	385	246	106	20	7
	Improved	414	642	404	216	55	18
	No change	274	438	336	142	50	15
	Worse	83	162	126	50	18	9
No pre-op OAB	Never present	831	1081	602	205	46	10
	New symptom	77	110	56	27	10	0
		1913	2818	1770	746	199	59
Pre-operat ve OAB %		52.5%	57.7%	62.8%	68.9%	71.9%	83.1%

Table 43: OAB symptoms per BMI to show the percentage of pre-operative OAB symptoms are higher with higher BMI

Grade of operator by BMI

BMI	18-<25	25-<30	30-<35	35-<40	40-<45	45-<50	50-65
Grade of operator (11,748)							
Consu tant	2,298 78.8%	3,376 77.3%	2,135 75.9%	915 76.3%	273 81.7%	77 83.7%	21 91.3%
Assoc ate Spec a st	5 0.2%	21 0.5%	18 0.6%	9 0.8%	1 0.3%	0 0.0%	0 0.0%
Subspec Tra nee (SST)	187 6.4%	299 6.8%	192 6.8%	86 7.2%	16 4.8%	3 3.3%	0 0.0%
Staff grade	37 1.3%	48 1.1%	43 1.5%	13 1.1%	6 1.8%	1 1.1%	0 0.0%
Spec a ty Tra nee (ST)	357 12.2%	564 12.9%	399 14.2%	160 13.3%	36 10.8%	10 10.9%	2 8.7%
FTSTA	1 0.0%	1 0.0%	1 0.0%	0 0.0%	1 0.3%	0 0.0%	0 0.0%
Other	33 1.1%	58 1.3%	26 0.9%	17 1.4%	1 0.3%	1 1.1%	0 0.0%
Tota	2,918	4,367	2,814	1,200	334	92	23

Table 44: Grade of operator by BMI category for RPT in pilot analysis

Anaesthetic by BMI

BMI	18-<25	25-<30	30-<35	35-<40	40-<45	45-<50	50-65
Anaesthet c							
GA	1021 63%	1508 65%	942 68%	402 64%	114 68%	30 70%	7 70%
Sp na	242 15%	355 15%	215 15%	106 17%	31 18%	7 16%	2 20%
LA	19 1%	22 1%	13 1%	5 1%	0 0%	1 2%	0 0%
LA + sedat on	301 19%	413 18%	199 14%	104 17%	22 13%	4 9%	1 10%
GA + Sp na	2 0%	3 0%	2 0%	0 0%	0 0%	0 0%	0 0%
GA + Ep dura	1 0%	1 0%	1 0%	1 0%	0 0%	0 0%	0 0%
GA + Cauda	14 1%	19 1%	11 1%	4 1%	0 0%	1 2%	0 0%
Unanswered	11 1%	11 0%	5 0%	3 0%	1 1%	0 0%	0 0%

Table 45: Anaesthetic by BMI category for RPT in pilot analysis

BMI and Patient Reported Outcomes: RPT: PGII

BMI		VMB/MB	LB/NC	Worse	Unanswered
15-<18	%	57.1	42.9	0	7
	N	4	3	0	
18 - <25	%	91.6	6.7	1.7	1035
	N	1748	127	33	
25 - <30	%	91.4	6.8	1.8	1613
	N	2549	190	49	
30 - <35	%	87.2	10.5	2.3	1089
	N	1526	183	40	
35 - <40	%	85.6	11.1	3.3	478
	N	626	81	24	
40 - <45	%	79.9	17.9	2.2	154
	N	147	33	4	
45 - <50	%	72.2	22.2	5.6	38
	N	39	12	3	
50-<65	%	73.3	26.7	0	9
	N	11	4	0	

Table 46: PGII by BMI category for RPT in pilot analysis

Stats for BMI vs PGII RPT

	18-25	**25-30**	Marg na Row Tota s
Better	1748 (1745.89) [0]	2549 (2551.11) [0]	4297
Not Better	160 (162.11) [0.03]	239 (236.89) [0.02]	399
Marg na Co umn Tota s	1908	2788	4696 (Grand Tota)
The ch -square stat st c s 0.0508. The p-va ue s .821691. Th s resu t s not s gn f cant at p < .05.			

Table 47: Chi² to compare PGII by BMI for RPT in pilot analysis

	18-25	**30-35**	Marg na Row Tota s
Better	1748 (1708.17) [0.93]	1526 (1565.83) [1.01]	3274
Not better	160 (199.83) [7.94]	223 (183.17) [8.66]	383
Marg na Co umn Tota s	1908	1749	3657 (Grand Tota)
The ch -square stat st c s 18.5381. The p-va ue s .000017. Th s resu t s s gn f cant at p < .05.			

Table 48: Chi² to compare PGII by BMI for RPT in pilot analysis

	18-25	**35-40**	Marg na Row Tota s
Better	1748 (1716.4) [0.58]	626 (657.6) [1.52]	2374
Not better	160 (191.6) [5.21]	105 (73.4) [13.6]	265
Marg na Co umn Tota s	1908	731	2639 (Grand Tota)
The ch -square stat st c s 20.9094. The p-va ue s .000005. Th s resu t s s gn f cant at p < .05.			

Table 49: Chi² to compare PGII by BMI for RPT in pilot analysis

	18-25	**40-45**	Marg na Row Tota s
Better	1748 (1728.33) [0.22]	147 (166.67) [2.32]	1895
not better	160 (179.67) [2.15]	37 (17.33) [22.34]	197
Marg na Co umn Tota s	1908	184	2092 (Grand Tota)
The ch -square stat st c s 27.0369. The p-va ue s . Th s resu t s s gn f cant at p < .05.			

Table 50: Chi² to compare PGII by BMI for RPT in pilot analysis

	18-25	**45-50**	Marg na Row Tota s
Better	1748 (1737.82) [0.06]	160 (170.18) [0.61]	1908
not better	39 (49.18) [2.11]	15 (4.82) [21.53]	54
Marg na Co umn Tota s	1787	175	1962 (Grand Tota)
The ch -square stat st c s 24.3083. The p-va ue s .000001. Th s resu t s s gn f cant at p<.05.			

Table 51: Chi² to compare PGII by BMI for RPT in pilot analysis

BMI and Patient Reported Outcomes: RPT: Change in SUI

N = 7197

Table 42: BMI and Change in SUI Symptoms RPT

BMI		Cured/ Improved	No change	Worse	Total	Never present	Un-answered
15-<18	N	6	1	0	7	0	7
	%	85.7	14.3	0.0			
18 - <25	N	1795	48	12	1855	45	1043
	%	96.8	2.6	0.6			
25 - <30	N	2633	63	15	2711	74	1615
	%	97.1	2.3	0.6			
30 - <35	N	1614	59	14	1687	56	1095
	%	95.7	3.5	0.8			
35 - <40	N	658	33	7	698	21	490
	%	94.3	4.7	1.0			
40 - <45	N	163	12	1	176	2	160
	%	92.6	6.9	0.5			
45 - <50	N	41	6	2	49	2	41
	%	83.7	12.2	4.1			
50-<65	N	12	2	0	14	1	9
	%	86.7	14.3	0.0			

Table 52: Change in SUI symptoms by BMI for RPT in pilot analysis

Stats to compare change in SUI by BMI for RPT in pilot analysis

	18-25	**25-30**	Marg na Row Tota s
Cured/ mproved SUI	1795 (1799.3) [0.01]	2663 (2658.7) [0.01]	4458
Not cur/ mproved SUI	60 (55.7) [0.33]	78 (82.3) [0.22]	138
Marg na Co umn Tota s	1855	2741	4596 (Grand Tota)
The chi-square statistic is 0.5743. The p-value is .448564. This result is not significant at p < .05.			

Table 53: Chi² to compare change in SUI by BMI for RPT in pilot analysis

	18-25	**30-35**	Marg na Row Tota s
Cured/ mproved SUI	1795 (1785.35) [0.05]	1614 (1623.65) [0.06]	3409
Not cur/ mproved SUI	60 (69.65) [1.34]	73 (63.35) [1.47]	133
Marg na Co umn Tota s	1855	1687	3542 (Grand Tota)
The chi-square statistic is 2.919. The p-value is .087541. This result is not significant at p < .05.			

Table 54: Chi² to compare change in SUI by BMI for RPT in pilot analysis

	18-25	**35-40**	Marg na Row Tota s
Cured/ mproved SUI	1795 (1782.34) [0.09]	658 (670.66) [0.24]	2453
Not cur/ mproved SUI	60 (72.66) [2.21]	40 (27.34) [5.86]	100
Marg na Co umn Tota s	1855	698	2553 (Grand Tota)
The chi-square statistic is 8.3965. The p-value is .00376. This result is significant at p < .05.			

Table 55: Chi² to compare change in SUI by BMI for RPT in pilot analysis

	18-25	**40-45**	Marg na Row Tota s
Cured/ mproved SUI	1795 (1788.33) [0.02]	163 (169.67) [0.26]	1958
Not cur/ mproved SUI	60 (66.67) [0.67]	13 (6.33) [7.04]	73
Marg na Co umn Tota s	1855	176	2031 (Grand Tota)
The chi-square statistic is 7.9968. The p-value is .004686. This result is significant at p < .05.			

Table 56: Chi² to compare change in SUI by BMI for RPT in pilot analysis

	18-25	**45-50**	Marg na Row Tota s
Cured/ mproved SUI	1795 (1788.75) [0.02]	41 (47.25) [0.83]	1836
Not cur/ mproved SUI	60 (66.25) [0.59]	8 (1.75) [22.32]	68
Marg na Co umn Tota s	1855	49	1904 (Grand Tota)
The chi-square statistic is 23.7596. The p-value is .000001. This result is significant at p < .05.			

Table 57: Chi² to compare change in SUI by BMI for RPT in pilot analysis

BMI and Patient Reported Outcomes: RPT: Change in OAB

N = 7123

Table 49: Outcomes of OAB vs BMI RPT

OAB	Total	New		Cured/ improved		No change		Worse		Never present		Total to analyse	Unanswered
BMI		N	%	N	%	N	%	N	%	N	%	N	N
15<18	14	0	0	3	42.9	3	42.9	0	0	1	14.3	7	7
18<25	2943	77	4.2	627	34.3	244	13.4	81	4.4	798	43.7	1827	1116
25<30	4401	108	4.0	990	36.7	392	14.6	155	5.8	1046	38.9	2691	1710
30<35	2838	55	3.3	632	37.5	300	17.8	123	7.3	573	34.0	1683	1155
35<40	1209	27	3.9	310	44.4	124	17.8	48	6.9	189	27.1	698	511
40<45	338	9	5.2	63	36.4	40	23.1	17	9.8	44	25.4	173	165
45<50	92	0	0	22	43.2	10	19.6	9	17.6	10	19.6	51	41
50<55	24	0	0	5	33.3	4	27.7	1	6.7	5	33.3	15	9

Table 58: Change in OAB symptoms by BMI for RPT in pilot analysis

BMI and Patient Reported Outcomes: RPT: Change in OAB – patients with pre-operative OAB

OAB		Cured	Improved	No change	Worse	Total
15<18	N	1	2	3	0	6
	%	16.7	33.3	50.0	0	
18<25	N	229	398	244	81	952
	%	24.1	41.8	25.6	8.5	
25<30	N	378	612	392	155	1537
	%	24.6	39.8	25.5	10.1	
30<35	N	243	389	300	123	1055
	%	23.0	36.9	28.4	11.7	
35<40	N	105	205	124	48	482
	%	21.8	42.5	25.7	10.0	
40<45	N	19	44	40	17	120
	%	15.8	36.7	33.3	14.2	
45<50	N	6	16	10	9	41
	%	14.6	39.0	24.4	22.0	
50<65	N	2	3	4	1	10
	%	20.0	30.0	40.0	10.0	

Table 59: Change in OAB symptoms by BMI for patients with *pre-operative OAB for RPT in pilot analysis*

Stats to compare change n OAB n pat ents w th pre-operat ve OAB by BMI for RPT n p ot ana ys s

	OAB worse	**OAB not worse**	*Row Totals*
18-<25	81 (90.27) [0.95]	871 (861.73) [0.10]	952
25-<30	155 (145.73) 0.59]	1382 (1391.27) 0.06]	1537
Column Totals	236	2253	2489 (Grand Tota)
The ch -square stat st c s 1.7017. The *p*-va ue s .192071. The resu t s *not* s gn f cant at $p < .05$.			

Table 60: Chi² to compare change in OAB in patient with *pre-operative OAB by BMI for RPT in pilot analysis*

	OAB worse	**OAB not worse**	*Row Totals*
18-<25	81 (96.77) [2.57]	871 (855.23) [0.29]	952
30-<35	123 (107.23) [2.32]	932 (947.77) [0.26]	1055
Column Totals	204	1803	2007 (Grand Tota)
The ch -square stat st c s 5.4392. The *p*-va ue s .01969. The resu t s s gn f cant at $p < .05$.			

Table 61: Chi² to compare change in OAB in patient with *pre-operative OAB by BMI for RPT in pilot analysis*

	OAB worse	**OAB not worse**	*Row Totals*
18-<25	81 (85.64) [0.25]	871 (866.36) [0.02]	952
35-<40	48 (43.36) 0.50]	434 (438.64) 0.05]	482
Column Totals	129	1305	1434 (Grand Tota)
The ch -square stat st c s 0.8219. The *p*-va ue s .364619. The resu t s *not* s gn f cant at $p < .05$.			

Table 62: Chi² to compare change in OAB in patient with *pre-operative OAB by BMI for RPT in pilot analysis*

	OAB worse	**OAB not worse**	*Row Totals*
18-<25	81 (87.03) [0.42]	871 (864.97) [0.04]	952
40-<45	17 (10.97) [3.31]	103 (109.03) [0.33]	120
Column Totals	98	974	1072 (Grand Tota)
The ch -square stat st c s 4.1077. The *p*-va ue s .042689. The resu t s s gn f cant at $p < .05$.			

Table 63: Chi² to compare change in OAB in patient with *pre-operative OAB by BMI for RPT in pilot analysis*

	OAB worse	**OAB not worse**	*Row Totals*
18-<25	81 (86.28) [0.32]	871 (865.72) [0.03]	952
45-<50	9 (3.72) 7.51]	32 (37.28) 0.75]	41
Column Totals	90	903	993 (Grand Tota)
The ch -square stat st c s 8.6183. The *p*-va ue s .003328. The resu t s s gn f cant at $p < .05$.			

Table 64: Chi² to compare change in OAB in patient with *pre-operative OAB by BMI for RPT in pilot analysis*

BMI and Patient Reported Outcomes: RPT: Change in OAB – patients without pre-operative OAB

		New symptom	Never present	Total
15<18	N	0	1	1
	%	0	100	
18<25	N	77	798	875
	%	8.8	91.2	
25<30	N	108	1046	1154
	%	9.4	90.6	
30<35	N	55	573	628
	%	8.8	91.2	
35<40	N	27	189	216
	%	12.5	87.5	
40<45	N	9	44	53
	%	17.0	83.0	
45<50	N	0	10	10
	%	0.0	100.0	
50<65	N	0	5	5
	%	0	100	

Table 65: Change in OAB symptoms by BMI for patients without *pre-operative OAB for RPT in pilot analysis*

Stats to compare change n OAB n pat ents w thout pre-operat ve OAB by BMI for RPT n p ot ana ys s

	New OAB	**Never present**	*Row Totals*
18-<25	77 (79.78) [0.10]	798 (795.22) [0.01]	875
25-<30	108 (105.22) 0.07]	1046 (1048.78) 0.01]	1154
Column Totals	185	1844	2029 (Grand Tota)
The ch -square stat st c s 0.1875. The *p*-va ue s .665005. The resu t s *not* s gn f cant at $p < .05$.			

Table 66: Chi² to compare change in OAB in patient without *pre-operative OAB by BMI for RPT in pilot analysis*

	New OAB	**Never present**	*Row Totals*
18-<25	77 (76.85) [0.00]	798 (798.15) [0.00]	875
30-<35	55 (55.15) [0.00]	573 (572.85) [0.00]	628
Column Totals	132	1371	1503 (Grand Tota)
The ch -square stat st c s 0.0008. The *p*-va ue s .977344. The resu t s *not* s gn f cant at $p < .05$.			

Table 67: Chi² to compare change in OAB in patient without *pre-operative OAB by BMI for RPT in pilot analysis*

	New OAB	**Never present**	*Row Totals*
18-<25	77 (83.41) [0.49]	798 (791.59) [0.05]	875
35-<40	27 (20.59) 2.00]	189 (195.41) 0.21]	216
Column Totals	104	987	1091 (Grand Tota)
The ch -square stat st c s 2.75. The *p*-va ue s .097252. The resu t s *not* s gn f cant at $p < .05$.			

Table 68: Chi² to compare change in OAB in patient without *pre-operative OAB by BMI for RPT in pilot analysis*

	New OAB	**Never present**	*Row Totals*
18-<25	77 (81.09) [0.21]	798 (793.91) [0.02]	875
40-<45	9 (4.91) [3.40]	44 (48.09) [0.35]	53
Column Totals	86	842	928 (Grand Tota)
The ch -square stat st c s 3.9778. The *p*-va ue s .046102. The resu t s s gn f cant at $p < .05$.			

Table 69: Chi² to compare change in OAB in patient without *pre-operative OAB by BMI for RPT in pilot analysis*

BMI and Patient Reported Outcomes: PUB: PGII

N = 429

BMI		VMB/MB	LB/NC	Worse
15-<18	N	0	0	0
	%	0.0%	0.0%	0.0%
18 - <25	N	53	38	5
	%	20.9%	23.5%	35.7%
25 - <30	N	85	58	3
	%	33.6%	35.8%	21.4%
30 - <35	N	58	36	2
	%	22.9%	22.2%	14.3%
35 - <40	N	36	13	3
	%	14.2%	8.0%	21.4%
40 - <45	N	16	13	1
	%	6.3%	8.0%	7.1%
45 - <50	N	5	4	0
	%	2.0%	2.5%	0.0%

Table 70: PGII by BMI category for PUB in pilot analysis

Stats for BMI vs PGII PUB

	18 - 25	**25 - 30**	Row Totals
Better	53 (54.74) [0.06]	85 (83.26) [0.04]	138
Not better	43 (41.26) [0.07]	61 (62.74) [0.05]	104
Column Totals	96	146	242 (Grand Total)
The chi-square statistic is 0.2142. The p-value is .643463. The result is not significant at p < .05.			

Table 71: Chi^2 to compare PGII by BMI for PUB in pilot analysis

	18 - 25	**30 - 35**	Row Totals
Better	53 (55.50) [0.11]	58 (55.50) [0.11]	111
Not better	43 (40.50) [0.15]	38 (40.50) [0.15]	81
Column Totals	96	96	192 (Grand Total)
The chi-square statistic is 0.5339. The p-value is .464986. The result is not significant at p < .05.			

Table 72: Chi^2 to compare PGII by BMI for PUB in pilot analysis

	18 - 25	**35 - 40**	Row Totals
Better	53 (57.73) [0.39]	36 (31.27) [0.72]	89
Not better	43 (38.27) [0.58]	16 (20.73) [1.08]	59
Column Totals	96	52	148 (Grand Total)
The chi-square statistic is 2.7666. The p-value is .096252. The result is not significant at p < .05.			

Table 73: Chi^2 to compare PGII by BMI for PUB in pilot analysis

	18 - 25	**45 - 50**	Row Totals
Better	53 (53.03) [0.00]	5 (4.97) [0.00]	58
Not better	43 (42.97) [0.00]	4 (4.03) [0.00]	47
Column Totals	96	9	105 (Grand Total)
The chi-square statistic is 0.0004. The p-value is .984019. The result is not significant at p < .05.			

Table 74: Chi^2 to compare PGII by BMI for PUB in pilot analysis

BMI and Patient Reported Outcomes: PUB: Change in SUI
N = 401

BMI		Cured	Improved	No change	Worse	Total
18-<25	N	23	47	17	2	89
	%	26	53	19	2	
25-<30	N	39	65	30	2	136
	%	29	48	22	1	
30-<35	N	24	46	19	1	90
	%	27	51	21	1	
35-<40	N	17	22	9	2	50
	%	34	44	18	4	
40-<45	N	10	11	5	1	27
	%	37	41	19	4	
45-<50	N	2	4	3	0	9
	%	22	44	33	0	
Total		115	195	83	8	

Table 75: Change in SUI symptoms by BMI for PUB in pilot analysis

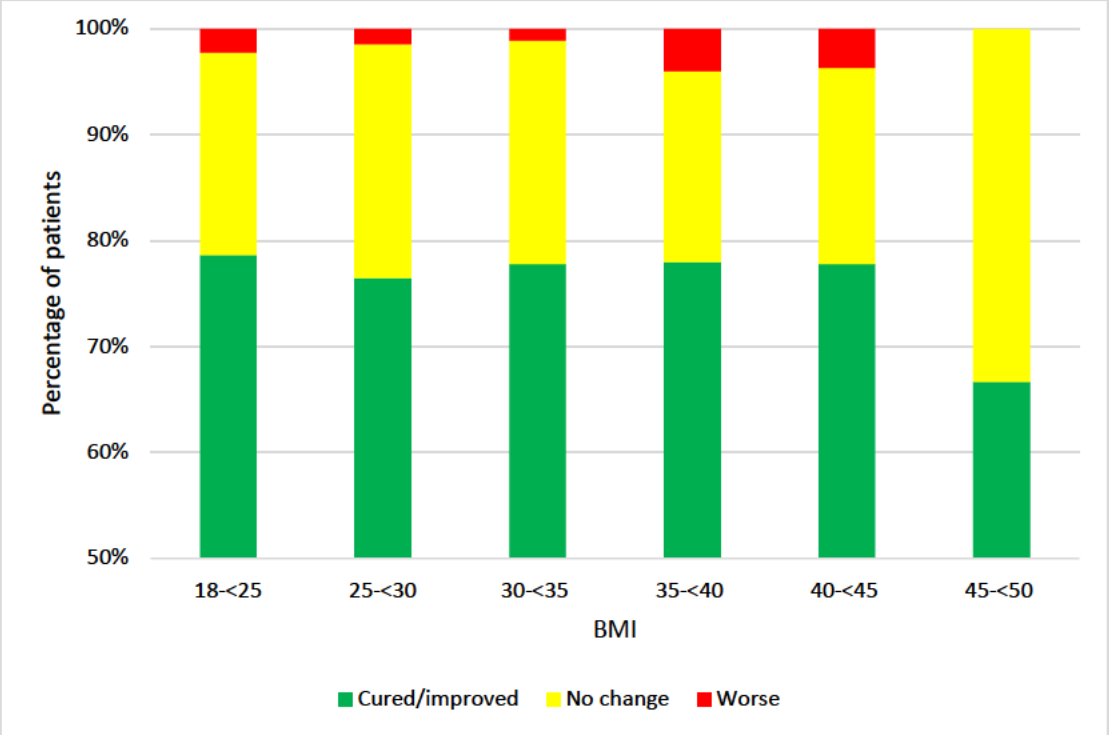


Figure 4: Outcomes reported using change in SUI for patients undergoing PUB, by BMI

BMI and Patient Reported Outcomes: PUB: Change in OAB – patients with pre-operative OAB
N=263

OAB		Cured	Improved	No change	Worse	Total
18-<25	N	5	16	30	2	53
	%	9%	30%	57%	4%	
25-<30	N	7	30	46	7	90
	%	8%	33%	51%	8%	
30-<35	N	3	15	36	3	57
	%	5%	26%	63%	5%	
35-<40	N	1	11	18	2	32
	%	3%	34%	56%	6%	
40-<45	N	1	11	10	1	23
	%	4%	48%	43%	4%	
45-<50	N	1	2	5	0	8
	%	13%	25%	63%	0%	

Table 76: Change in OAB symptoms by BMI for patients with *pre-operative OAB for PUB in pilot analysis (n=263)*

BMI and Patient Reported Outcomes: PUB: Change in OAB – patients without pre-operative OAB

		Never present	New symptom	Total
18-<25	N	33	0	33
	%	100%	0%	
25-<30	N	35	2	37
	%	95%	5%	
30-<35	N	29	1	30
	%	97%	3%	
35-<40	N	16	0	16
	%	100%	0%	
40-<45	N	2	1	3
	%	67%	33%	
45-<50	N	0	0	0
	%	na	na	

Table 77: Change in OAB symptoms by BMI for patients without pre-operative OAB for PUB in pilot analysis (n=119)

PFMT outcomes

RPT - Unanswered for PFMT = 2253

PGII RPT - 6027 removed as no answer for PGII

	V much better		Much better		A little better		No change		A little worse		Much worse		V much worse		
No	669	8.6%	197	11.1%	66	12.9%	27	10.5%	7	10.3%	10	13.7%	6	16.7%	
Yes - declined	262	3.4%	79	4.5%	11	2.1%	17	6.6%	1	1.5%	2	2.7%	4	11.1%	
Yes - accepted	6832	88.0%	1496	84.4%	436	85.0%	214	82.9%	60	88.2%	61	83.6%	26	72.2%	
	7763		1772		513		258		68		73		36		10483

Table 78: PGII by PFMT performed category for RPT in pilot analysis

SUI RPT - 6728 removed as no answer for SUI

	Cured		Improved		No change		Worse		Never present		
No	619	8.2%	228	13.8%	24	9.2%	7	12.7%	52	22.5%	
Yes – declined	226	3.0%	59	3.6%	14	5.4%	5	9.1%	7	3.0%	
Yes – accepted	6738	88.9%	1365	82.6%	223	85.4%	43	78.2%	172	74.5%	
	7583		1652		261		55		231		9786

Table 79: Change in SUI symptoms by PFMT performed category for RPT in pilot analysis

OAB - 7025 removed as no answer for OAB

	Cured		Improved		No change		Worse		Never present		New symptom		
No	145	9.5%	272	12.3%	159	10.9%	60	10.8%	249	7.4%	32	9.0%	
Yes - declined	54	3.5%	60	2.7%	43	2.9%	16	2.9%	119	3.5%	12	3.4%	
Yes - accepted	1328	87.0%	1879	85.0%	1260	86.2%	479	86.3%	3007	89.1%	311	87.6%	
	1527		2211		1462		555		3375		355		9485

Table 80: Change in OAB symptoms by PFMT performed category for RPT in pilot analysis

PUB - 256 removed as no answer for PFMT

PGII - 486 – removed as no PGII

	V much better		Much better		A little better		No change		A little worse		Much worse		V much worse		
No	28	12.3%	27	16.7%	15	13.5%	22	17.6%	3	21.4%	0	0.0%	0	0	
Yes - declined	6	2.6%	2	1.2%	4	3.6%	5	4.0%	2	14.3%	0	0.0%	0	0	
Yes - accepted	194	85.1%	133	82.1%	92	82.9%	98	78.4%	9	64.3%	5	100.0%	0	0	
	228		162		111		125		14		5		0		645

Table 81: PGII by PFMT performed category for PUB in pilot analysis

SUI - 564 removed as unanswered for SUI

	Cured		Improved		No change		Worse		Never present		
No	22	12.8%	36	13.8%	22	17.9%	3	27.3%	0		
Yes - declined	2	1.2%	7	2.7%	4	3.3%	2	18.2%	1	33.3%	
Yes - accepted	148	86.0%	215	83.3%	97	78.9%	6	54.5%	2	66.7%	
	172		258		123		11		3		567

Table 82: Change in SUI symptoms by PFMT performed category for PUB in pilot analysis

OAB - 601 removed as no OAB

	Cured		Improved		No change		Worse		Never present		New symptom		
No	5	17.9%	17	15.0%	32	16.8%	1	5.9%	21	11.9%	1	20.0%	
Yes - declined	2	7.1%	1	0.9%	7	3.7%	1	5.9%	4	2.3%	0	0.0%	
Yes - accepted	21	75.0%	95	84.1%	151	79.5%	15	88.2%	152	85.9%	4	80.0%	
	28		113		190		17		177		5		530

Table 83: Change in OAB symptoms by PFMT performed category for PUB in pilot analysis

Urodynamics
Effect of UDS on PGII for RPT

	US (13195)	US and voiding dysfunction (437)	Normal (471)	Mixed (2669)	Mixed and Voiding dysfunction (108)	DOA (74)	Voiding dysfunction (7)	Mixed with overflow/chronic retention (4)
	N % Excluding unanswered							
Very much better	6234 74 8%	219 73 6%	236 72 2%	1069 66 6%	46 66 7%	24 51 1%	4 100 0%	2 100 0%
Much better	1429 17 2%	40 13 5%	58 17 7%	313 19 5%	13 18 8%	13 27 7%	0 0 0%	0 0 0%
A little better	361 4 3%	22 7 4%	18 5 5%	118 7 4%	4 5 8%	5 10 6%	0 0 0%	0 0 0%
No change	174 2 1%	8 2 4%	10 3 1%	71 4 4%	4 5 8%	3 6 4%	0 0 0%	0 0 0%
A little worse	57 0 7%	2 0 7%	3 0 9%	11 0 7%	1 1 4%	0 0 0%	0 0 0%	0 0 0%
Much worse	46 0 6%	3 1 0%	2 0 6%	18 1 1%	1 1 4%	2 4 3%	0 0 0%	0 0 0%
Very much worse	28 0 3%	4 1 4%	0 0 0%	4 0 2%	0 0 0%	0 0 0%	0 0 0%	0 0 0%
Total to analyse	8329	298	327	1604	71	47	4	2
Unanswered	4866	147	144	1065	39	33	3	2

Table 84: PGII by UDS category for RPT in pilot analysis

UDS	Total	Better	%	Neutral	%	Worse	%
USI	8329	7663	92.0%	535	6.4%	131	1.6%
USI + voiding dysfunction	296	258	87.2%	29	9.8%	9	3.0%
Normal	327	294	89.9%	28	8.6%	5	1.5%
Mixed	1604	1382	86.2%	189	11.8%	33	2.1%
Mixed and voiding dysfunction	69	59	85.5%	8	11.6%	2	2.9%
DOA	44	34	77.3%	8	18.2%	2	4.5%
Shaded excluded as too few patients							
UDS	Total	Better	%	Neutral	%	Worse	%
USI and overflow/chronic retention	2	1	50%	1	50%	0	0
Voiding dysfunction	4	4	100.0%	0	0.0%	0	0.0%
DOA + voiding dysfunction	3	3	100.0%	0	0.0%	0	0.0%
Mixed with overflow/chronic retention	2	2	100%	0	0.0%	0	0.0%
Over flow/chronic retention	0	0	0.0%	0	0.0%	0	0.0%

Table 85: PGII by UDS category for RPT in pilot analysis

Stats to compare PGII between UDS for RPT

	Better (VMB and MB)	**Not better (LB, NC + worse)**	Tota s
No DO	8221 (8137) [0.87]	738 (822) [8.58]	8959
Any DO	1480 (1564) [4.51]	242 (158) [44.66]	1722
Tota s	9701	980	10681
The chi-square statistic is 58.6268. This result is significant at p < .05.			

Table 86: Chi2 test to compare PGII by UDS: No DO vs any DO for RPT in pilot analysis

	Better	**Not better**	Row Tota s
No UDS	248 (239.81) [0.28]	13 (21.19) [3.16]	261
USI	7663 (7671.19) [0.01]	686 (677.81) [0.10]	8349
Co umn Tota s	7911	699	8610 (Grand Tota)
The chi-square statistic is 3.5523. The p-value is 0.59463. The result is not significant at p<.05.			

Table 87: Chi2 test to compare No UDS to USI on UDS for RPT in pilot analysis

Effect of UDS on change in SUI for RPT

UDS	Total	Cured	Improved	No change	Worse	Never present	Unanswered
USI	7848	6144 (78.3%)	1273 (16.2%)	193 (2.5%)	42 (0.5%)	196 (2.5%)	5346
USI + vo d ng dysfunct on	299	229 (76.6%)	50 (16.7%)	10 (3.3%)	5 (1.7%)	5 (1.7%)	138
Norma	308	249 (80.8%)	48 (15.6%)	9 (2.9%)	1 (0.3%)	1 (0.3%)	163
M xed	1524	1140 (74.8%)	304 (19.9%)	59 (3.9%)	10 (0.7%)	11 (0.7%)	1145
M xed & vo d ng dysfunct on	67	42 (62.7%)	20 (29.9%)	4 (6.0%)	0 (0.0%)	1 (1.5%)	41
DOA	42	28 (66.7%)	8 (19.0%)	2 (4.8%)	1 (2.4%)	3 (7.1%)	32
Shaded excluded as too few patients							
USI & overf ow/ chron c retent on	2	0 (0.0%)	1 (50.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	6
Vo d ng dysfunct on	4	4 (100%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3
DOA + vo d ng dysfunct on	3	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)	3
M xed w th overf ow/ chron c retent on	2	1 (50.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2
Over f ow/chron c retent on	0	0 (0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0

Table 88: Change in SUI outcome by UDS category for RPT in pilot analysis

Effect of UDS on change in OAB for RPT

UDS	Total Data	Cured	Improved	TOTAL Cure + improve	No change	Worse	New symptom	Never present	No Pre-op OAB symptm	Unanswered
USI	7559	1167 15.4%	1651 (21.8%)	**37.2%**	1035 (13.7%)	413 (5.5%)	323 (4.3%)	2970 (39.5%)	**43.8**	5636
USI + voiding dysfunctn	282	57 (20.2%)	74 (26.2%)	**46.4%**	43 (15.2%)	20 (7.1%)	6 (2.1%)	82 (29.1%)	**31.2**	437
Normal	292	37 (12.7%)	38 (13.0%)	**25.7%**	42 (14.4%)	18 (6.2%)	17 (5.8%)	140 (47.9%)	**53.7**	179
Mixed	1494	297 (19.9%)	511 (34.2%)	**54.1%**	342 (22.9%)	121 (8.1%)	23 (1.5%)	200 (13.4%)	**14.9**	1175
Mixed & voiding dysfunctn	67	13 (19.4%)	18 (26.9%)	**46.3**	21 (31.3%)	1 (1.5%)	2 (3.0%)	12 (17.9%)	**20.9**	41
DOA	43	3 (7.0%)	14 32.6%)	**39.6%**	11 (25.6%)	7 (16.3%)	0 (0.0%)	8 (18.6%)	**18.6**	31
Shaded excluded as too few patients										
USI and overflow/chronic retention	2	0 (0.0%)	1 (50.0%)		1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		6
Voiding dysfunction	4	1 (25.0%)	0 (0.0%)		1 (25.0%)	0 (0.0%)	0 (0.0%)	2 (50.0%)		3
DOA + voiding dysfunction	3	1 (33.0%)	0 (0.0%)		0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)		3
Mixed with overflow/chronic retention	1	0 (0.0%)	1 100%		0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3
Overflow/chronic retention	0	0 (0.0%)	0 (0.0%)		0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0

Table 89: Change in OAB outcome by UDS category for RPT in pilot analysis

Effect of UDS on change in OAB in patients with pre-op OAB for RPT

		Cured	Improved	No change	Worse	Total
USI	N	1167	1651	1035	413	4266
	%	27.40%	38.70%	24.30%	9.70%	
USI + voiding dysfunction	N	57	75	44	20	196
	%	29.10%	38.30%	22.40%	10.20%	
Normal	N	37	38	42	18	135
	%	27.40%	28.10%	31.10%	13.30%	
Mixed	N	297	511	342	121	1271
	%	23.40%	40.20%	26.90%	9.50%	
Mixed + voiding dysfunction	N	13	19	21	1	54
	%	24.10%	35.20%	38.90%	1.90%	
DOA	N	4	14	11	7	36
	%	11.10%	38.90%	30.60%	19.40%	

Table 90: Change in OAB outcome by UDS category for patients with *pre-operative OAB symptoms for RPT in pilot analysis*

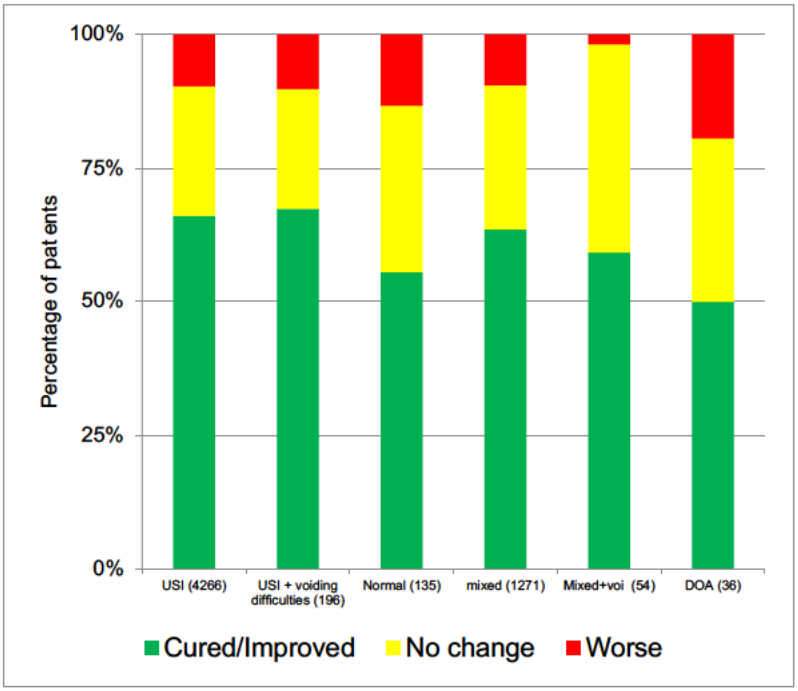


Figure 5: Change in OAB symptoms by UDS category for patients with *pre-op OAB symptoms for RPT in pilot analysis*

Effect of UDS on change in OAB in patients without pre-op OAB for RPT

		Never present	New symptom	Total
USI	N	2970	323	3293
	%	90.20%	9.80%	
USI + voiding dysfunction	N	82	6	88
	%	93.20%	6.80%	
Normal	N	140	17	157
	%	89.20%	10.80%	
Mixed	N	200	23	223
	%	89.70%	10.30%	
Mixed + voiding dysfunction	N	12	2	14
	%	85.70%	14.30%	
DOA	N	10	0	10
	%	100%	0.00%	

Table 91: Change in OAB outcome by UDS category for patients without *pre-operative OAB symptoms for RPT in pilot analysis*

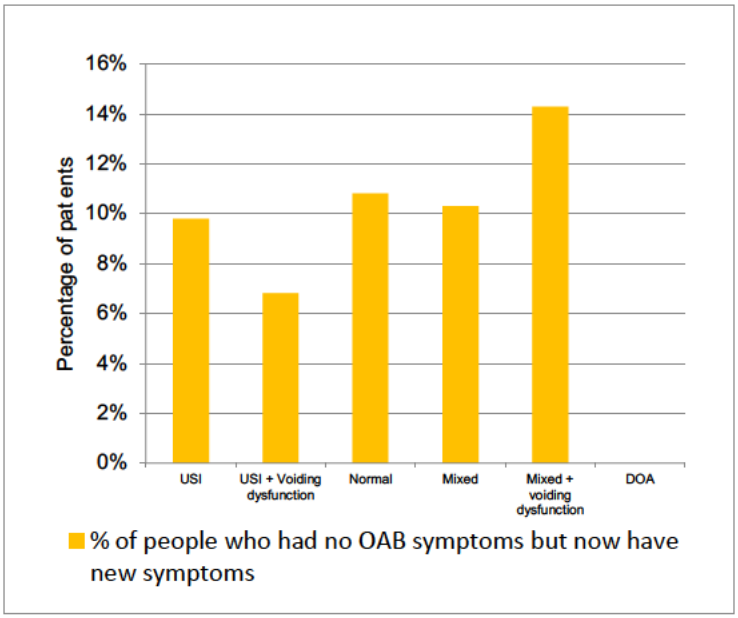


Figure 6: New OAB symptoms with no pre-op OAB symptoms for RPT by UDS in pilot analysis

Urodynamics
Effect of UDS on PGII for PUB

PGII	Better	Neutral	Worse
USI (431)	61.72%	35.50%	2.78%
USI + Voiding dysfunction (35)	65.71%	34.29%	0.00%
Normal (26)	46.15%	46.15%	7.69%
Any DOA (142)	54.93%	40.85%	4.23%

Table 92: PGII by UDS category for PUB in pilot analysis

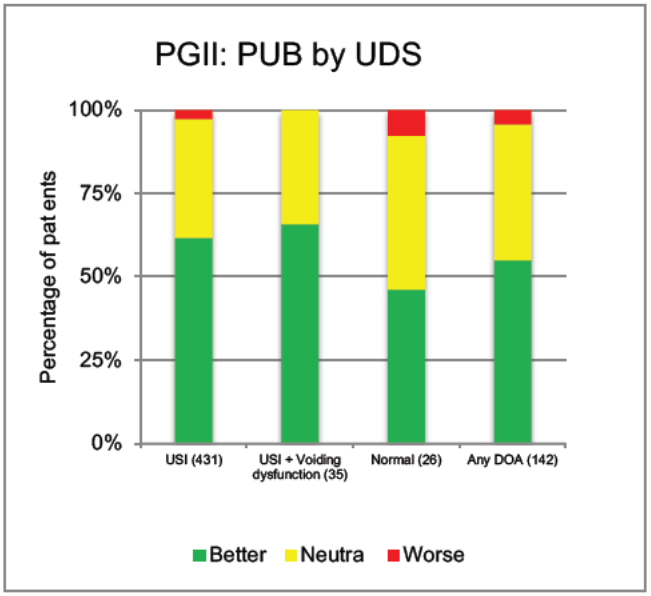


Figure 7: PGII outcomes for PUB by UDS in pilot analysis

Effect of UDS on change in SUI for PUB

Change in SUI	Cured	Improved	No change	Worse	Never present	New symptom
USI (385)	29.10%	48.30%	20.30%	1.30%	1.00%	0.00%
USI, Voiding dysfunction (34)	32.40%	44.10%	20.60%	2.90%	0.00%	0.00%
Normal (23)	13.00%	52.20%	34.80%	0.00%	0.00%	0.00%
Any DOA (129)	31.00%	38.00%	28.70%	1.60%	0.80%	0.00%

Table 93: Change in SUI outcome by UDS category for PUB in pilot analysis

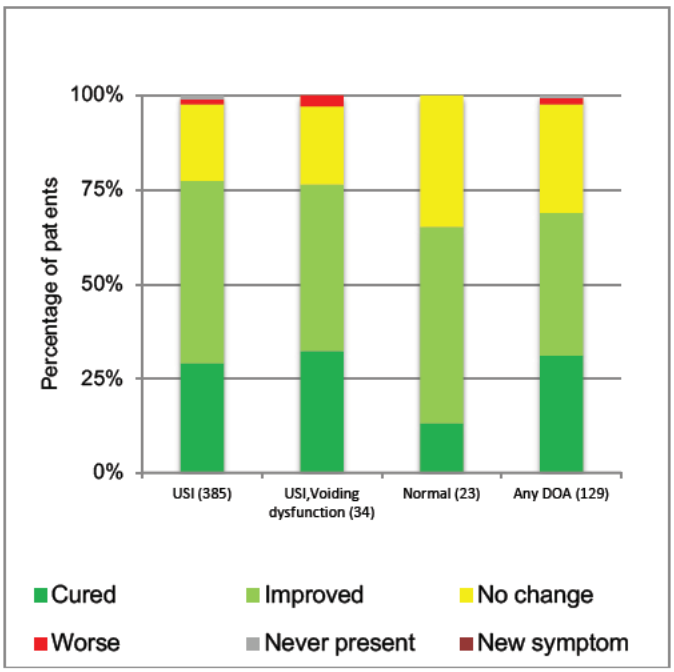


Figure 8: Change in SUI symptoms by UDS for PUB in pilot analysis

Effect of UDS on change in OAB in patients with pre-op OAB for PUB

Change in OAB	Cured	Improved	No change	Worse	Never present	New symptom
USI (358)	4.20%	17.30%	30.40%	3.10%	45.00%	0.00%
USI, Voiding dysfunction (32)	6.30%	40.60%	37.50%	0.00%	6.30%	9.40%
Normal (20)	0.00%	10.00%	35.00%	10.00%	45.00%	0.00%
Any DOA (125)	8.00%	30.40%	50.40%	5.60%	5.60%	0.00%

Table 94: Change in OAB outcome by UDS category for PUB in pilot analysis

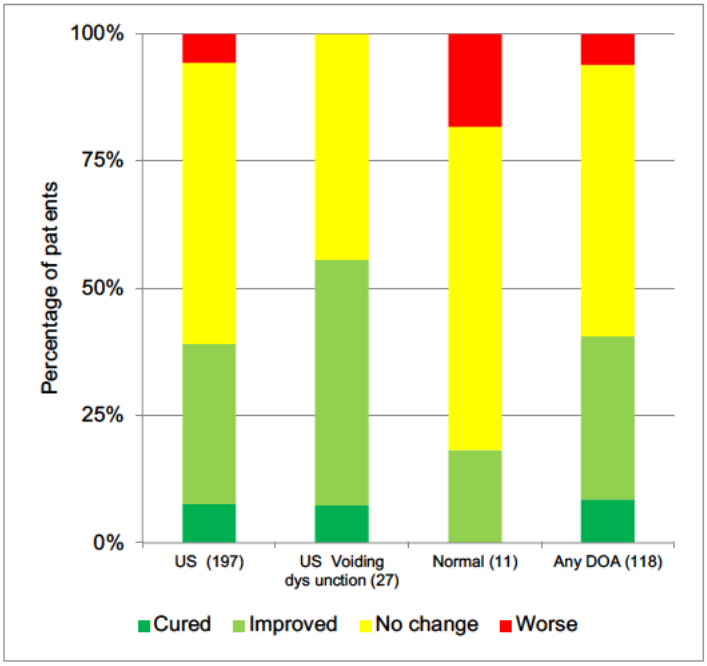


Figure 9: Change in OAB symptoms by UDS for PUB in pilot analysis

Outcome by grade of operator

RPT - PGII (n = 11255)

PGII	Consultant		Associate Specialist		Subspec trainee		Speciality Trainee		Staff Grade		FTSTA		Other	
Very much better	6572	73.4%	11	57.9%	503	75.1%	1037	74.4%	63	63.0%	4	66.7%	84	74.3%
Much better	1577	17.6%	5	26.3%	103	15.4%	237	17.0%	23	23.0%	0	0.0%	16	14.2%
A tt e better	445	5.0%	2	10.5%	32	4.8%	57	4.1%	7	7.0%	0	0.0%	5	4.4%
No change	224	2.5%	0	0.0%	18	2.7%	34	2.4%	3	3.0%	1	16.7%	4	3.5%
A tt e worse	48	0.5%	0	0.0%	11	1.6%	11	0.8%	1	1.0%	0	0.0%	2	1.8%
Much worse	59	0.7%	1	5.3%	0	0.0%	15	1.1%	1	1.0%	1	16.7%	1	0.9%
Very much worse	28	0.3%	0	0.0%	3	0.4%	3	0.2%	2	2.0%	0	0.0%	1	0.9%
Tota	8953		19		670		1394		100		6		113	

Table 95: PGII by grade of operator for RPT in pilot analysis

	Consultant	Trainee	Marg na Row Tota s
Improved GII	8149	1880	10563
Not Improved GII	804	184	454
Marg na Co umn Tota s	8953	2064	11017
The ch -square stat st c s 0.0088. The p-va ue s .925197. The resu t s not s gn f cant at p < .05.			

Table 96: Chi^2 to compare the difference of PGII between trainees (ST&SST) and consultants RPT in pilot analysis

Outcome by grade of operator

RPT - Change in SUI (n = 10686)

	Consultant		Associate Specialist		Subspec trainee		Speciality Trainee		Staff Grade		FTSTA		Other	
New symptom	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Cured	6485	77.7%	7	46.7%	510	76.7%	1059	78.9%	64	67.4%	6	85.7%	82	74.5%
Improved	1423	17.0%	5	33.3%	102	15.3%	214	15.9%	24	25.3%	0	0.0%	17	15.5%
No change	223	2.7%	0	0.0%	13	2.0%	42	3.1%	3	3.2%	0	0.0%	5	4.5%
worse	43	0.5%	0	0.0%	5	0.8%	8	0.6%	3	3.2%	1	14.3%	2	1.8%
never present	173	2.1%	3	20.0%	35	5.3%	20	1.5%	1	1.1%	0	0.0%	4	3.6%
n/a	1	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
tota	8348		15		665		1343		95		7		110	

Table 97: Change in SUI by grade of operator for RPT in pilot analysis

	Consultant	Trainee	Marg na Row Tota s
SUI better	7908	1885	9793
SUI not better	266	68	334
Marg na Co umn Tota s	8174	1953	10127
The ch -square stat st c s 0.256. The p-va ue s .612854. The resu t s not s gn f cant at p < .05.			

Table 98: Chi^2 to compare the difference of change of SUI symptoms between trainees (ST&SST) and consultants RPT in pilot analysis

Outcome by grade of operator

RPT - Change in OAB (n = 10191)

	Consu tant		Assoc ate Spec a st		Subspec tra nee		Spec a ty Tra nee		Staff Grade		FTSTA		Other	
New symptom	295	3.7%	2	25.0%	21	3.4%	66	5.1%	4	4.3%	0	0.0%	4	3.7%
Cured	1393	17.3%	0	0.0%	51	8.2%	149	11.6%	18	19.4%	1	14.3%	14	13.1%
Improved	1888	23.4%	1	12.5%	136	22.0%	296	23.1%	26	28.0%	1	14.3%	27	25.2%
No change	1212	15.0%	3	37.5%	119	19.2%	204	15.9%	13	14.0%	0	0.0%	11	10.3%
worse	454	5.6%	0	0.0%	52	8.4%	83	6.5%	6	6.5%	2	28.6%	5	4.7%
never present	2832	35.1%	2	25.0%	240	38.8%	485	37.8%	26	28.0%	3	42.9%	46	43.0%
n/a	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
tota	8074		8		619		1283		93		7		107	

Table 99: Change in OAB by grade of operator for RPT in pilot analysis

Outcome by grade of operator

PUB - PGII (n = 11255)

	Consu tant		Assoc ate Spec a st		Subspec Tra nee(SST)		Spec a ty Tra nee (ST)		Staff grade		Other		
Unanswered	524		3		41		48		6		2		
VMB	217	34.1%	0	0.0%	12	28.6%	12	31.6%	3	23.1%	1	50.0%	
MB	161	25.3%	0	0.0%	13	31.0%	11	28.9%	2	15.4%	0	0.0%	
LB	110	17.3%	1	100%	7	16.7%	8	21.1%	5	38.5%	0	0.0%	
NC	129	20.3%	0	0.0%	7	16.7%	5	13.2%	3	23.1%	1	50.0%	
LW	13	2.0%	0	0.0%	2	4.8%	1	2.6%	0	0.0%	0	0.0%	
MW	3	0.5%	0	0.0%	1	2.4%	1	2.6%	0	0.0%	0	0.0%	
VMW	3	0.5%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	
Sum	1160	100%	4	100%	83	100%	86	100%	19	100%	4	100%	1361
Sum unanswered	636		1		42		38		13		2		732

Table 100: PGII by grade of operator for PUB in pilot analysis

	No return to theatre	**Return to theatre**	Marg na Row Tota s
Consu tant	10202	53(0.5%)	10,255
Non-consu tant	2,311	31(1.3%)	2,342
Marg na Co umn Tota s	12,513	84	12,597
Pearson ch 2(1) = 18.7377 Pr = 0.000			

Table 101: Chi2 test: Return to theatre <72hr consultant vs non consultant: RPT in pilot analysis

Bladder perforation

Bladder perforation effect on outcome: PGII
(n=11204 available data) RPT
Unanswered for perforation = 269 Unanswered for PGII = 7290

	No perforation		Perforation	
Better (VMB+MB)	9892	91.0%	297	89.2%
No change (LB+NC)	797	7.3%	31	9.3%
Worse (LW,MW,VMW)	182	1.7%	5	1.5%

Table 102: PGII (grouped) by presence of bladder perforation for RPT in pilot analysis

Table 22

	No perforation	**Perforation**	Marg na Row Tota s
PGII better	9892	297	10189
PGII not better	979	36	1015
Marg na Co umn Tota s	10871	333	11204
The ch -square stat st c s 1.278. The p-va ue s .258266. The resu t s not s gn f cant.			

Table 103: Chi^2 test to assess the implication of bladder perforation on PGII for RPT in pilot analysis

Bladder perforation effect on outcome: SUI

	No perforation		**Perforation**	
SUI better	9760	96.7%	292	93.9%
SUI not better	330	3.3%	19	6.1%

Table 104: Change in SUI (grouped) by presence of bladder perforation for RPT in pilot analysis

	No perforation	**Perforation**	Marg na Row Tota s
SUI better	9760	292	10052
SUI not better	330	19	349
Marg na Co umn Tota s	10090	311	10401
The ch -square stat st c s 7.4973. The p-va ue s 0.006. Th s resu t s s gn f cant at p < .05.			

Table 105: Chi2 test to assess the implication of bladder perforation on change in SUI for RPT in pilot analysis

Exploration of bladder perforation: RPT

BMI and perforat on RPT
Upon ana ys s of 11859 cases w th comp eted BMI data, 11830 recorded data on the presence or absence of b adder perforat on.

	Perf	**No perf**	Marg na Row Tota s
BMI Under 25	137 (95.72) [17.8]	2812 (2853.28) [0.6]	2949
BMI Over 25	247 (288.28) [5.91]	8634 (8592.72) [0.2]	8881
Marg na Co umn Tota s	384	11446	11830 (Grand Tota)
The ch -square stat st c s 24.5034. The p-va ue s .000001. Th s resu t s s gn f cant at p < .05.			

Table 106: Chi² test to compare perforation rate in patients with a BMI <25 vs perforation rate for those patients with BMI >25 following RPT in pilot analysis

Table 51: BMI Grouped – bladder perforation comparison RPT

BMI	**Perforation**	**No perforation**	**% Perforation**	**P value compared to 18-25**	**Unanswered (excluded)**
15-<18	1	13	7.1%	NS 0.66	0
18 - <25	136	2799	4.6%	NA	8
25 - <30	159	4226	3.6%	*0.032	16
30 - <35	57	2767	2.0%	*<0.05	14
35 - <40	18	1189	1.5%	*0.00	2
40 - <45	8	327	2.4%	NS 0.057	3
45 - <50	3	89	3.3%	NS 0.5	0
50-<65	1	23	4.2%	NS 0.91	0

Table 107: Bladder perforation rate per BMI Grouped for RPT in pilot analysis

Stats for BMI groups and perforation RPT

	BMI 18-<25	**BMI 15-<18**	Marg na Row Tota s
Perf	136 (136.35) [0]	1 (0.65) [0.19]	137
No perf	2799 (2798.65) [0]	13 (13.35) [0.01]	2812
Marg na Co umn Tota s	2935	14	2949 (Grand Tota)
The ch -square stat st c s 0.198. The p-va ue s .65632. Th s resu t s not s gn f cant at p < .05.			

Table 108: Chi² test to compare perforation rate following RPT to BMI group of 18-25 in pilot analysis

	BMI 18-<25	**BMI 25-<30**	Marg na Row Tota s
Perf	136 (118.28) [2.65]	159 (176.72) [1.78]	295
No perf	2799 (2816.72) [0.11]	4226 (4208.28) [0.07]	7025
Marg na Co umn Tota s	2935	4385	7320 (Grand Tota)
The ch -square stat st c s 4.6165. The p-va ue s .031666. Th s resu t s s gn f cant at p < .05.			

Table 109: Chi² test to compare perforation rate following RPT to BMI group of 18-25 in pilot analysis

	BMI 18-<25	BMI 30-<35	Marg na Row Tota s
Perf	136 (98.36) [14.4]	57 (94.64) [14.97]	193
No perf	2799 (2836.64) [0.5]	2767 (2729.36) [0.52]	5566
Marg na Co umn Tota s	2935	2824	5759 (Grand Tota)
The ch -square stat st c s 30.3926. Th s resu t s s gn f cant at p < .05.			

Table 110: Chi² test to compare perforation rate following RPT to BMI group of 18-25 in pilot analysis

	BMI 18-<25	BMI 35-<40	Marg na Row Tota s
Perf	136 (109.12) [6.62]	18 (44.88) [16.1]	154
No perf	2799 (2825.88) [0.26]	1189 (1162.12) [0.62]	3988
Marg na Co umn Tota s	2935	1207	4142 (Grand Tota)
The ch -square stat st c s 23.5929. The p-va ue s .000001. Th s resu t s s gn f cant at p < .05.			

Table 111: Chi² test to compare perforation rate following RPT to BMI group of 18-25 in pilot analysis

	BMI 18-<25	BMI 40-45	Marg na Row Tota s
Perf	136 (129.25) [0.35]	8 (14.75) [3.09]	144
No perf	2799 (2805.75) [0.02]	327 (320.25) [0.14]	3126
Marg na Co umn Tota s	2935	335	3270 (Grand Tota)
The ch -square stat st c s 3.602. The p-va ue s .057711. Th s resu t s not s gn f cant at p < .05.			

Table 112: Chi² test to compare perforation rate following RPT to BMI group of 18-25 in pilot analysis

	BMI 18-<25	BMI 45-<50	Marg na Row Tota s
Perf	136 (134.78) [0.01]	3 (4.22) [0.36]	139
No perf	2799 (2800.22) [0]	89 (87.78) [0.02]	2888
Marg na Co umn Tota s	2935	92	3027 (Grand Tota)
The ch -square stat st c s 0.3838. The p-va ue s .535602. Th s resu t s not s gn f cant at p < .05.			

Table 113: Chi² test to compare perforation rate following RPT to BMI group of 18-25 in pilot analysis

	BMI 18-<25	BMI 50-<65	Marg na Row Tota s
Perf	136 (135.89) [0]	1 (1.11) [0.01]	137
No perf	2799 (2799.11) [0]	23 (22.89) [0]	2822
Marg na Co umn Tota s	2935	24	2959 (Grand Tota)
The ch -square stat st c s 0.0118. The p-va ue s .913641. Th s resu t s not s gn f cant at p < .05.			

Table 114: Chi² test to compare perforation rate following RPT to BMI group of 18-25 in pilot analysis

Grade of operator and Perforation rate

Table 19: % perforation by grade of operator RPT

Grade	Number	Perforation	%
Consultant	14156	313	2.2%
Associate Specialist	64	1	1.6%
Staff Grade	201	16	8.0%
Subspeciality trainee	1140	62	5.4%
Specialty trainee	2549	228	8.9%
Other	190	9	4.7%
Unanswered	194	10	5.2%

Table 115: Percentage perforation rate by grade of operator for RPT in pilot analysis

	Consultant	**Trainee (SST + ST)**	Marg na Row Tota s
Perf	313 (478.35) [57.15]	290 (124.65) [219.32]	603
No perf	13843 (13677.65) [2]	3399 (3564.35) [7.67]	17242
Marg na Co umn Tota s	14156	3689	17845 (Grand Tota)
The ch -square stat st c s 286.1397. The p-va ue s < .001. Th s resu t s s gn f cant at p < .05.			

Table 116: Chi² test to compare the bladder perforation rates of consultants and trainees for RPT in pilot analysis

Comparison between First and repeat PUB
PGII

PGII	First	Repeat	Marg na Row Tota s
Better (VMB&MB)	255 (250.35) [0.09]	165 (169.65) [0.13]	420
Not better (others)	170 (174.65) [0.12]	123 (118.35) [0.18]	293
Marg na Co umn Tota s	425	288	713 (Grand Tota)
The ch -square stat st c s 0.5202. The p-va ue s .470763. Th s resu t s not s gn f cant at p < .05.			

Table 117: Chi2 test to compare First vs Repeat PUB for PGII in pilot analysis

Change in SUI	First PUB		Repeat PUB	
Cured	27.63%	105	29.7%	76
Improved	48.68%	185	42.2%	108
No change	21.84%	83	24.2%	62
Worse	1.32%	5	2.7%	7
Never present	0.53%	2	1.2%	3
New symptom	0.00%	0	0%	0
Unanswered				

Table 118: Change in SUI with first and repeat PUB in pilot analysis

Tab e 89

Change n SUI	First	Repeat	Marg na Row Tota s
Cured	105 (108.14) [0.09]	76 (72.86) [0.14]	181
Not cured	275 (271.86) [0.04]	180 (183.14) [0.05]	455
Marg na Co umn Tota s	380	256	636 (Grand Tota)
The ch -square stat st c s 0.3175. The p-va ue s .573088. Th s resu t s not s gn f cant at p < .05.			

Table 119: Chi^2 test to compare change in SUI symptoms (cured vs not cured) between first and repeat PUB in pilot analysis

Change n SUI	First	Repeat	Marg na Row Tota s
Cured/ mproved	290 (283.21) [0.16]	184 (190.79) [0.24]	474
Not cured/ mproved	90 (96.79) [0.48]	72 (65.21) [0.71]	162
Marg na Co umn Tota s	380	256	636 (Grand Tota)
The ch -square stat st c s 1.5889. The p-va ue s .207478. Th s resu t s not s gn f cant at p < .05.			

Table 120: Chi^2 test to compare change in SUI symptoms (cured/improved vs not cured/improved) between first and repeat PUB in pilot analysis

Appendix 5: Further information about inclusion and exclusion criteria (Chapter 3)

It was important to maximise the number of patients included in the analysis without compromising the data used. There were multiple options for this:

1. All data from every centre
    a. Good points: maximise the data
    b. Bad points: as shown in the funnel plot in the pilot analysis there are centres with minimal case entries making it unlikely those centres have entered all their data
2. Only BSUG accredited units
    a. Good points
        i. > 60% outcome reporting required to become accredited
        ii. >90% cases included to become accredited however this clause only started in 2016 so prior to this there is no guarantee of high completion rates
    b. Bad points
        i. Accreditation only started in 2013
        ii. Some units use the database but opted not to become accredited
        iii. Due to the anonymising it is not possible to identify units to know which are accredited
3. Only use the data from BSUG accredited centres after the date that centre gained accreditation status

    Discussion as above
4. Only those centres with certain percentage of completed data points
    a. Good points – more likely to be complete and unbiased

b. Bad points – data loss

5. “High volume centres” – only centres with a certain number of cases per year included (>10? >50?) as suggested in the BSUG questionnaire
    a. Good points
        i. High volume units
        ii. Likely to be entering all their cases onto the database so limit the bias
    b. Bad points
        i. Exclude data

To improve the quality of the data various inclusion criteria were considered with respect to numbers of procedures performed by the centre. Consideration was given firstly to only including those centres that performed >10 mesh tapes in any given year. The numbers included were calculated using this suggestion however it soon became evident that this inadvertently excluded new centres that had signed up after 2015 which is when there was a major decline in mesh tapes leading to the governmental pause. As they had not achieved 10 mesh tapes per year since joining they were excluded which meant large numbers of the other alternative procedures data was lost as well (Figure 1). Further options were considered:

1. keep all data from centres who joined after 2015
2. Keep all data from centres who joined after 2015 if they did >10/year of any of the incontinence procedures (i.e. 3 PUB + 4 colposuspension + 4 AFS = 11) as this would then be equivalent to the 10 tape procedures before.
3. Adjust the inclusion criteria to include all centres if they did >10/year of any of the incontinence procedures (i.e. 3 PUB + 4 colposuspension + 4 AFS = 11) as this would then be equivalent to the 10 tape procedures before

After further thought, in conjunction with external expert informal discussion, the inclusion criteria was set to include centres if they did ≥10/year of any of the incontinence procedures added together (i.e. RPT + PUB + colposuspension + AFS ≥10 in any one year) as this would then be equivalent to the ≥10 mesh tape procedures before (Figure 2).

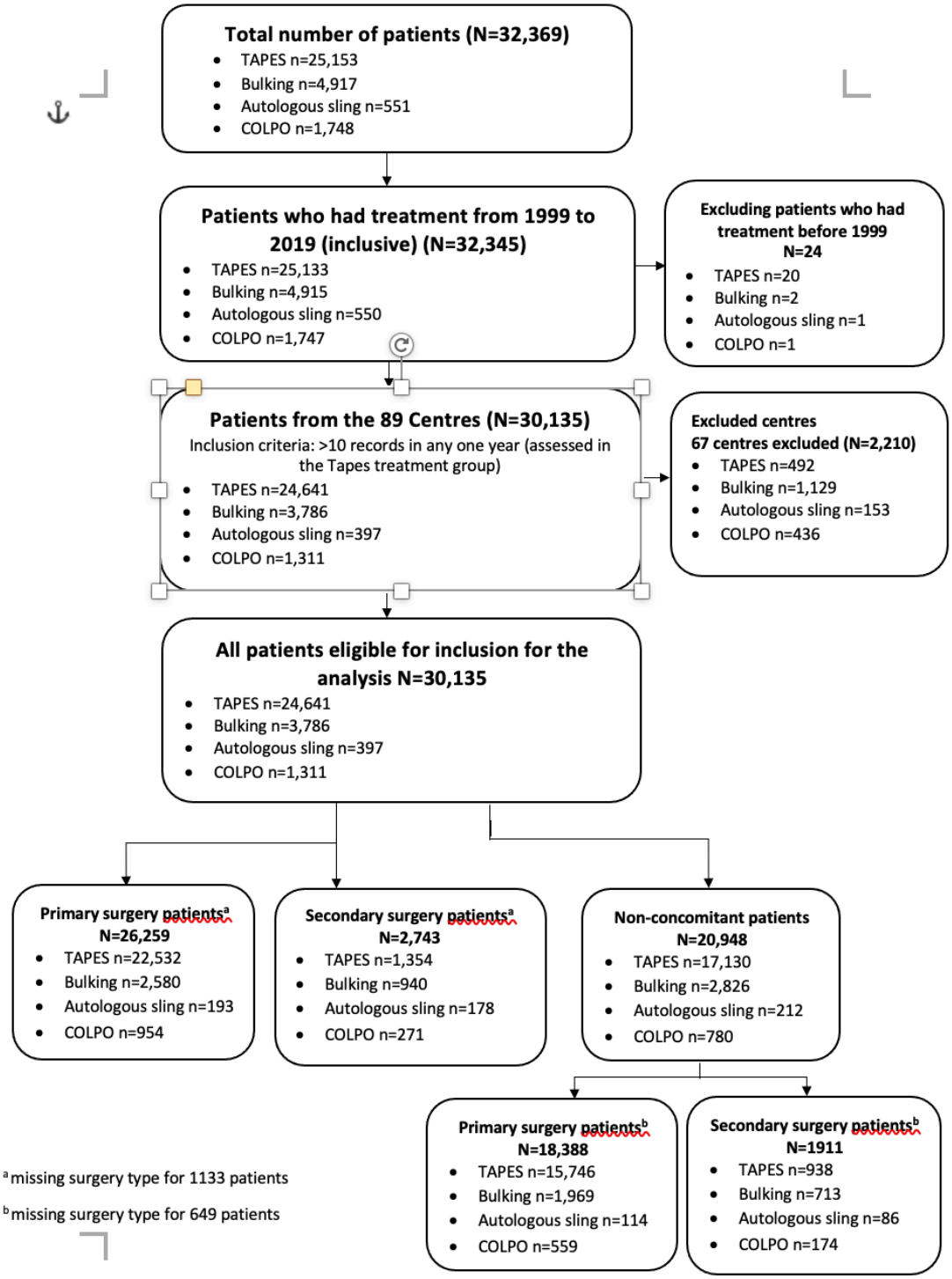


Figure 1: >10 tapes/year in any one year

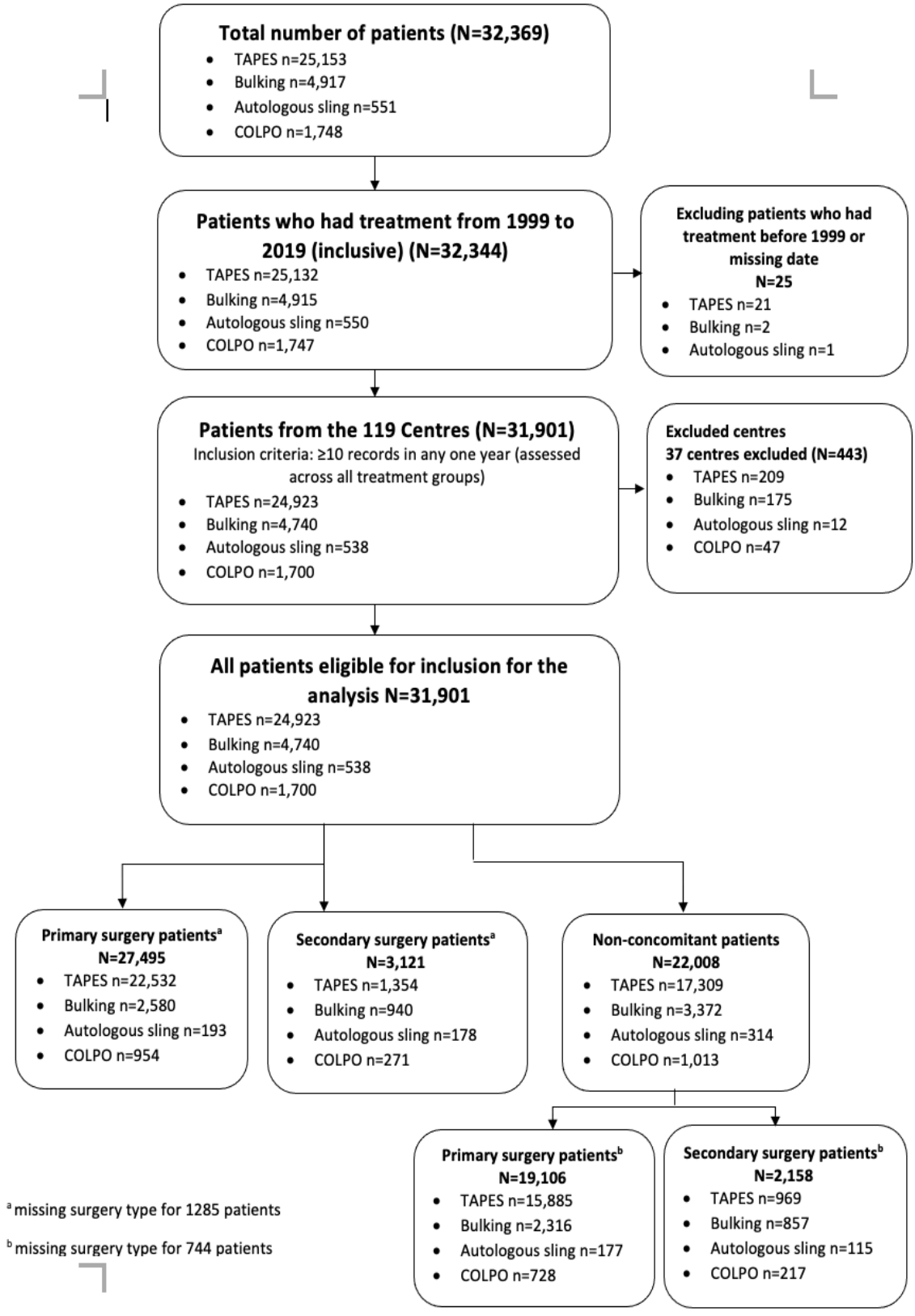


Figure 2: >10 of any incontinence surgery/year in any one year

Appendix 6: Rationalising UDS results for use in the multivariable analysis.
There were too many pre-operative urodynamic diagnoses to include in the multivariable analysis (table 1), so they were regrouped into six larger groups (table 2).

Table 1: Initial list of UDS diagnoses

1. USI
2. USI + Voiding dysfunction
3. USI, Overflow/chronic retention,
4. Occult USI
5. Occult USI, Voiding dysfunction
6. Normal
7. Mixed USI+DOA
8. Mixed USI+DOA, Voiding dysfunction
9. Mixed USI+DOA, Overflow/chronic retention
10. DOA
11. DOA, Occult USI
12. DOA, Voiding dysfunction
13. Voiding dysfunction
14. Overflow/chronic retention
15. Not completed

Table 2: Reduced list of UDS diagnoses

1. All USI and USI + voiding dysfunction
2. Normal
3. Mixed & Mixed and voiding dysfunction
4. DOA
5. Not completed
6. Voiding dysfunction/ Overflow/chronic retention

However when the analyses were run using these six groups there were errors, and some analyses took several days and did not complete due to convergence issues. This was likely because of the resultant small sample sizes after being divided into six different UDS groups. A decision was made to further reduce the number of categories (table 3).

Table 3: Final list of UDS diagnoses

1. USI and USI + voiding dysfunction
2. DOA, Mixed and Mixed and voiding dysfunction
3. Not completed, Normal, Voiding dysfunction

Appendix 7:
Primary population
Primary analysis: Comparison across procedures:
Crude odds ratios, Univariable and multivariable analysis

Tables

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Table 9: Univariable and Multivariable analysis readmitted to hospital primary population 18

Assessment across treatments: Primary population
Crude odds ratio with unadjusted data

Popu at on: Non concom tant f rst surgery		
Outcome measure	**OR (95% CI)**	**p value**
PGII n=11,825		
RPT	Reference	
PUB	0.13 (0.11,0.15)	<0.001
AFS	0.81 (0.37,1.77)	0.593
Co posuspens on	0.69 (0.51,0.93)	0.014
Constant	10.09 (9.43,10.81)	
SUI symptoms n=11,072		
RPT	Reference	
PUB	0.10 (0.08,0.12)	<0.001
AFS	1.01 (0.25,4.14)	0.991
Co posuspens on	0.99 (0.56,1.74)	0.967
Constant	29.27 (26.14,32.76)	
OAB (Patients with pre-operative symptoms) n=6,427		
RPT	Reference	
PUB	0.38 (0.32,0.45)	<0.001
AFS	0.34 (0.17,0.70)	0.003
Co posuspens on	0.51 (0.39,0.67)	<0.001
Constant	1.66 (1.57,1.75)	
OAB (Patients without pre-operative symptoms) n=4,374		
RPT	Reference	
PUB	0.22 (0.12,0.42)	<0.001
AFS	1.72 (0.59,5.03)	0.324
Co posuspens on	1.54 (0.97,2.44)	0.07
Constant	0.11 (0.10,0.12)	

Tab e *1*: Unadjusted odds rat os pr mary popu at on

Univariable and Multivariable analysis of primary population
Outcomes of PGII, SUI, OAB, bladder injury, return to hospital and readmitted to hospital.

Primary outcome:	**Populations: Non concomitant and primary surgery patients**			
Global impression of improvement Not better vs Better				
Not better = A little better, No change, a little worse, much worse, very much worse				
Better = Very much better, much better				
The combination of variables and outcome did not use imputed data, therefore results are based on non-imputed data (i.e. original data)				
Multivariable analysis (accounting for Centre as a random effect)		Number of imputations	0	
Characteristics	**OR**	**95% CI**	**p value**	**n=5122**
Treatment				
RPT	Reference			
PUB	0.13	(0.09,0.17)	<0.001	
AFS	1.12	(0.25,4.93)	0.882	
Colposuspension	0.96	(0.56,1.65)	0.874	
Age (decades)	0.89	(0.83,0.95)	0.001	
BMI	0.95	(0.93,0.97)	<0.001	
Pelvic floor exercises	1.09	(0.83,1.44)	0.534	
Pre operative urodynamic diagnosis				
USI, USI and voiding dysfunction	Reference			
DOA, Mixed, mixed and voiding dysfunction	0.62	(0.50,0.77)	<0.001	
Normal, voiding dysfunction, not completed	0.85	(0.57,1.27)	0.435	
Grade of operator				
Consultant	Reference			
Other (Associate specialist, subspec trainee, speciality trainee, other, staff grade, FTSTA)	0.96	(0.76,1.20)	0.702	
Bladder injury	0.61	(0.38,0.98)	0.042	
Univariable analysis (accounting for Centre as a random effect)		Number of imputations	66	
Characteristic	**OR**	**95% CI**	**p value**	**n=11825**
Treatment				
RPT	Reference			
PUB	0.10	(0.09,0.12)	<0.001	
AFS	0.69	(0.30,1.55)	0.367	
Colposuspension	0.67	(0.48,0.92)	0.014	
Characteristic	**OR**	**95% CI**	**p value**	**n=11606**

Age (decades)	0.81	(0.78,0.85)	<0.001	
Characteristic	**OR**	**95% CI**	**p value**	**n=8072**
BMI	0.95	(0.94,0.97)	<0.001	
Characteristic	**OR**	**95% CI**	**p value**	**n=10972**
Pelvic floor exercises	1.16	(0.96,1.40)	0.113	
Characteristic	**OR**	**95% CI**	**p value**	**n=11390**
Pre operative urodynamic diagnosis				
USI, USI and voiding dysfunction	Reference			
DOA, Mixed, mixed and voiding dysfunction	0.61	(0.52,0.70)	<0.001	
Normal, voiding dysfunction, not completed	0.83	(0.64,1.07)	0.154	
Characteristic	**OR**	**95% CI**	**p value**	**n=11716**
Grade of operator				
Consultant	Reference			
Other (Associate specialist, subspec trainee, speciality trainee, other, staff grade, FTSTA)	1.02	(0.88,1.19)	0.761	
Characteristic	**OR**	**95% CI**	**p value**	**n=11700**
Bladder injury	1.06	(0.75,1.50)	0.735	

Tab e 2: Un var ab e and Mu t var ab e ana ys s PGII pr mary popu at on

Secondary outcome:	**Populations: Non concomitant and primary surgery patients**			
Change of stress urinary incontinence				
No change or worse vs Cured or improved				
The combination of variables and outcome did not use imputed data, therefore results are based on non-imputed data (i.e. original data)				
Multivariable analysis (accounting for Centre as a random effect)		Number of imputations	0	
Characteristics	**OR**	**95% CI**	**pvalue**	**n=4993**
Treatment				
RPT	Reference			
PUB	0.10	(0.06,0.14)	<0.001	
AFS	0.26	(0.06,1.17)	0.079	
Colposuspension	1.04	(0.40,2.72)	0.933	
Age (decades)	0.81	(0.73,0.90)	<0.001	
BMI	0.96	(0.94,0.99)	0.005	
Pelvic floor exercises	0.96	(0.63,1.47)	0.860	
Pre operative urodynamic diagnosis				
USI, USI and voiding dysfunction	Reference			
DOA, Mixed, mixed and voiding dysfunction	0.78	(0.56,1.09)	0.140	
Normal, voiding dysfunction, not completed	0.99	(0.53,1.84)	0.966	
Grade of operator				
Consultant	Reference			
Other (Associate specialist, subspec trainee, speciality trainee, other, staff grade, FTSTA)	0.85	(0.60,1.20)	0.350	
Bladder injury	0.57	(0.27,1.20)	0.138	
Univariable analysis (accounting for Centre as a random effect)		Number of imputations	66	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=11072**
Treatment				
RPT	Reference			
PUB	0.08	(0.06,0.09)	<0.001	
AFS	0.89	(0.21,3.76)	0.874	
Colposuspension	0.95	(0.53,1.71)	0.859	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=10953**
Age (decades)	0.77	(0.72,0.82)	<0.001	

Characteristic	**OR**	**95% CI**	**pvalue**	**n=7865**
BMI	0.96	(0.94,0.98)	<0.001	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=10186**
Pelvic floor exercises	1.26	(0.96,1.65)	0.092	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=10681**
Pre operative urodynamic diagnosis				
USI, USI and voiding dysfunction	Reference			
DOA, Mixed, mixed and voiding dysfunction	0.70	(0.56,0.86)	0.001	
Normal, voiding dysfunction, not completed	0.78	(0.54,1.14)	0.200	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=10970**
Grade of operator				
Consultant	Reference			
Other (Associate specialist, subspec trainee, speciality trainee, other, staff grade, FTSTA)	0.99	(0.80,1.24)	0.961	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=11030**
Bladder injury	0.79	(0.49,1.26)	0.314	

Tab e *3*: Un var ab e and Mu t var ab e ana ys s change n SUI pr mary popu at on

Secondary outcome:	**Populations: Non concomitant and primary surgery patients**			
Change in Urgency/Urge incontinence- patients with pre-operative OAB symptoms				
No change or worse vs Cured or improved				
The combination of variables and outcome did not use imputed data, therefore results are based on non-imputed data (i.e. original data)				
Multivariable analysis (accounting for Centre as a random effect)		Number of imputations	0	
Characteristics	**OR**	**95% CI**	**pvalue**	**n=2848**
Treatment				
RPT	Reference			
PUB	1.24	(0.86,1.80)	0.254	
AFS	0.61	(0.12,3.06)	0.550	
Colposuspension	0.99	(0.60,1.65)	0.970	
Age (decades)	1.00	(0.94,1.08)	0.916	
BMI	0.99	(0.97,1.01)	0.190	
Pelvic floor exercises	0.89	(0.67,1.18)	0.407	
Pre operative urodynamic diagnosis				
USI, USI and voiding dysfunction	Reference			
DOA, Mixed, mixed and voiding dysfunction	0.97	(0.79,1.18)	0.731	
Normal, voiding dysfunction, not completed	1.17	(0.76,1.79)	0.485	
Grade of operator				
Consultant	Reference			
Other (Associate specialist, subspec trainee, speciality trainee, other, staff grade, FTSTA)	0.99	(0.80,1.22)	0.896	
Bladder injury	1.01	(0.62,1.63)	0.982	
Univariable analysis (accounting for Centre as a random effect)		Number of imputations	66	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=6427**
Treatment				
RPT	Reference			
PUB	0.59	(0.48,0.73)	<0.001	
AFS	0.46	(0.21,1.00)	0.051	
Colposuspension	0.94	(0.68,1.29)	0.681	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=6367**
Age (decades)	0.97	(0.93,1.01)	0.148	

Characteristic	OR	95% CI	pvalue	n=4571
BMI	0.99	(0.97,1.00)	0.074	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=5948**
Pelvic floor exercises	0.85	(0.70,1.03)	0.105	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=6121**
Pre operative urodynamic diagnosis				
USI, USI and voiding dysfunction	Reference			
DOA, Mixed, mixed and voiding dysfunction	0.94	(0.82,1.07)	0.350	
Normal, voiding dysfunction, not completed	0.97	(0.72,1.30)	0.819	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=6360**
Grade of operator				
Consultant	Reference			
Other (Associate specialist, subspec trainee, speciality trainee, other, staff grade, FTSTA)	0.94	(0.81,1.08)	0.383	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=6396**
Bladder injury	1.09	(0.78,1.50)	0.622	

Tab e *4*: Un var ab e and Mu t var ab e ana ys s change n OAB w th pre-op OAB pr mary popu at on

Secondary outcome:	**Populations: Non concomitant and primary surgery patients**			
Change in Urgency/Urge incontinence- patients with no pre-operative OAB symptoms				
Never present vs New symptoms				
The combination of variables and outcome did not use imputed data, therefore results are based on non-imputed data (i.e. original data)				
Multivariable analysis (accounting for Centre as a random effect)		Number of imputations	0	
Characteristics	**OR**	**95% CI**	**pvalue**	**n=2070**
Treatment				
RPT	Reference			
PUB	0.20	(0.05,0.84)	0.028	
AFS	2.53	(0.51,12.68)	0.259	
Colposuspension	1.11	(0.46,2.66)	0.822	
Age (decades)	1.21	(1.06,1.38)	0.006	
BMI	1.02	(0.99,1.05)	0.258	
Pelvic floor exercises	0.94	(0.56,1.58)	0.815	
Pre operative urodynamic diagnosis				
USI, USI and voiding dysfunction	Reference			
DOA, Mixed, mixed and voiding dysfunction	1.03	(0.57,1.85)	0.930	
Normal, voiding dysfunction, not completed	0.94	(0.52,1.68)	0.824	
Grade of operator				
Consultant	Reference			
Other (Associate specialist, subspec trainee, speciality trainee, other, staff grade, FTSTA)	1.46	(1.02,2.10)	0.041	
Bladder injury	1.47	(0.72,3.02)	0.294	
Univariable analysis (accounting for Centre as a random effect)		Number of imputations	66	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=6427**
Treatment				
RPT	Reference			
PUB	0.59	(0.48,0.73)	<0.001	
AFS	0.46	(0.21,1.00)	0.051	
Colposuspension	0.94	(0.68,1.29)	0.681	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=4325**
Age (decades)	1.06	(0.97,1.16)	0.203	

Characteristic	**OR**	**95% CI**	**pvalue**	**n=3269**
BMI	1.02	(0.99,1.04)	0.265	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=4041**
Pelvic floor exercises	0.91	(0.63,1.33)	0.641	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=4221**
Pre operative urodynamic diagnosis				
USI, USI and voiding dysfunction	Reference			
DOA, Mixed, mixed and voiding dysfunction	1.12	(0.73,1.72)	0.591	
Normal, voiding dysfunction, not completed	0.96	(0.63,1.45)	0.839	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=4343**
Grade of operator				
Consultant	Reference			
Other (Associate specialist, subspec trainee, speciality trainee, other, staff grade, FTSTA)	1.42	(1.10,1.83)	0.007	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=4364**
Bladder injury	1.12	(0.63,1.99)	0.705	

Tab e *5*: Un var ab e and Mu t var ab e ana ys s change n OAB w thout pre-op OAB pr mary popu at on

Secondary outcome:	**Populations: Non concomitant and primary surgery patients**			
Bladder injury				
Yes vs No				
Multivariable analysis (accounting for Centre as a random effect)		Number of imputations	66	
Characteristics	**OR**	**95% CI**	**pvalue**	**n=10251**
Treatment				
RPT	Reference			
PUB	0.03	(0.00,0.19)	<0.001	
AFS	1.45	(0.50,4.25)	0.496	
Colposuspension	0.92	(0.50,1.68)	0.776	
Age (decades)	1.10	(1.00,1.22)	0.060	
BMI	0.93	(0.91,0.96)	<0.001	
Pre operative urodynamic diagnosis				
USI, USI and voiding dysfunction	Reference			
DOA, Mixed, mixed and voiding dysfunction	0.80	(0.56,1.15)	0.230	
Normal, voiding dysfunction, not completed	0.55	(0.29,1.04)	0.065	
Grade of operator				
Consultant	Reference			
Other (Associate specialist, subspec trainee, speciality trainee, other, staff grade, FTSTA)	3.72	(2.88,4.80)	<0.001	
Univariable analysis (accounting for Centre as a random effect)		Number of imputations	66	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=18883**
Treatment				
RPT	Reference			
PUB	0.02	(0.01,0.10)	<0.001	
AFS	0.71	(0.29,1.73)	0.449	
Colposuspension	0.80	(0.51,1.27)	0.346	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=18472**
Age (decades)	1.09	(1.01,1.16)	0.018	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=10906**
BMI	0.94	(0.91,0.96)	<0.001	

Characteristic	OR	95% CI	pvalue	n=17752
Pre operative urodynamic diagnosis				
USI, USI and voiding dysfunction	Reference			
DOA, Mixed, mixed and voiding dysfunction	0.90	(0.71,1.13)	0.361	
Normal, voiding dysfunction, not completed	0.58	(0.37,0.93)	0.024	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=18683**
Grade of operator				
Consultant	Reference			
Other (Associate specialist, subspec trainee, speciality trainee, other, staff grade, FTSTA)	3.63	(3.02,4.36)	<0.001	

Tab e *6*: Un var ab e and Mu t var ab e ana ys s b adder njury pr mary popu at on

Secondary outcome:	**Populations: Non concomitant and primary surgery patients**			
Return to theatre for procedure-related event within 72 hours				
Yes vs No				
Unab e to be comp eted				
Multivariable analysis (accounting for Centre as a random effect)		Number of imputations	?	
Characteristics	**OR**	**95% CI**	**pvalue**	
Treatment				
RPT	Reference			
PUB	0.00	(0.00,0.00)	<0.001	
AFS	0.00	(0.00,0.00)	<0.001	
Colposuspension	0.00	(0.00,0.00)	<0.001	
Age (decades)	0.00	(0.00,0.00)	<0.001	
BMI	0.00	(0.00,0.00)	<0.001	
Pre operative urodynamic diagnosis				
USI, USI and voiding dysfunction	Reference			
DOA, Mixed, mixed and voiding dysfunction	0.00	(0.00,0.00)	<0.001	
Normal, voiding dysfunction, not completed	0.00	(0.00,0.00)	<0.001	
Grade of operator				
Consultant	Reference			
Other (Associate specialist, subspec trainee, speciality trainee, other, staff grade, FTSTA)	0.00	(0.00,0.00)	<0.001	
Bladder injury	0.00	(0.00,0.00)	<0.001	
Univariable analysis (accounting for Centre as a random effect)		Number of imputations	66	
Characteristic	**OR**	**95% CI**	**pvalue**	
Treatment				
RPT	Reference			
PUB	0.00	(0.00,0.00)	<0.001	
AFS	0.00	(0.00,0.00)	<0.001	
Colposuspension	0.00	(0.00,0.00)	<0.001	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=13205**
Age (decades)	0.80	(0.63,1.00)	0.053	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=8818**
BMI	0.97	(0.90,1.03)	0.303	

Characteristic	**OR**	**95% CI**	**pvalue**	**n=12953**
Pre operative urodynamic diagnosis				
USI, USI and voiding dysfunction	Reference			
DOA, Mixed, mixed and voiding dysfunction	0.60	(0.27,1.34)	0.212	
Normal, voiding dysfunction, not completed	1.29	(0.45,3.69)	0.630	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=13336**
Grade of operator				
Consultant	Reference			
Other (Associate specialist, subspec trainee, speciality trainee, other, staff grade, FTSTA)	3.88	(2.26,6.66)	<0.001	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=13325**
Bladder injury	5.43	(2.58,11.41)	<0.001	

Tab e 7: Un var ab e and Mu t var ab e ana ys s return to theatre pr mary popu at on

Secondary outcome:	**Populations: Non concomitant and primary surgery patients**			
Return to hospital within 30 days for procedure related event				
Yes vs No				
Multivariable analysis (accounting for Centre as a random effect)		Number of imputations	66	
Characteristics	**OR**	**95% CI**	**pvalue**	**n=4032**
Treatment				
RPT	Reference			
PUB	0.32	(0.19,0.53)	<0.001	
AFS	2.42	(1.07,5.45)	0.033	
Colposuspension	1.05	(0.62,1.78)	0.848	
Age (decades)	1.10	(0.97,1.23)	0.131	
BMI	0.99	(0.96,1.03)	0.607	
Pre operative urodynamic diagnosis				
USI, USI and voiding dysfunction	Reference			
DOA, Mixed, mixed and voiding dysfunction	0.89	(0.60,1.31)	0.550	
Normal, voiding dysfunction, not completed	1.41	(0.80,2.49)	0.240	
Grade of operator				
Consultant	Reference			
Other (Associate specialist, subspec trainee, speciality trainee, other, staff grade, FTSTA)	1.27	(0.88,1.82)	0.199	
Bladder injury	1.70	(0.88,3.28)	0.116	
Univariable analysis (accounting for Centre as a random effect)		Number of imputations	66	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=4981**
Treatment				
RPT	Reference			
PUB	0.25	(0.16,0.40)	<0.001	
AFS	2.52	(1.24,5.10)	0.010	
Colposuspension	1.01	(0.64,1.59)	0.964	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=4943**
Age (decades)	0.98	(0.89,1.08)	0.706	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=4263**
BMI	0.99	(0.96,1.03)	0.642	

Characteristic	OR	95% CI	pvalue	n=4733
Pre operative urodynamic diagnosis				
USI, USI and voiding dysfunction	Reference			
DOA, Mixed, mixed and voiding dysfunction	0.98	(0.70,1.37)	0.905	
Normal, voiding dysfunction, not completed	1.43	(0.89,2.30)	0.136	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=4933**
Grade of operator				
Consultant	Reference			
Other (Associate specialist, subspec trainee, speciality trainee, other, staff grade, FTSTA)	1.27	(0.93,1.74)	0.131	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=4959**
Bladder injury	2.45	(1.45,4.14)	0.001	

Tab e *8*: Un var ab e and Mu t var ab e ana ys s return to hosp ta pr mary popu at on

Secondary outcome:	**Populations: Non concomitant and primary surgery patients**			
Readmitted to hospital within 30 days for procedure related event				
Yes vs No				
Multivariable analysis (accounting for Centre as a random effect)		Number of imputations	66	
Characteristics	**OR**	**95% CI**	**pvalue**	**n=8207**
Treatment				
RPT	Reference			
PUB	0.22	(0.10,0.47)	<0.001	
AFS	5.81	(2.64,12.75)	<0.001	
Colposuspension	1.56	(0.93,2.61)	0.092	
Age (decades)	1.11	(1.00,1.22)	0.052	
BMI	1.01	(0.98,1.03)	0.560	
Pre operative urodynamic diagnosis				
USI, USI and voiding dysfunction	Reference			
DOA, Mixed, mixed and voiding dysfunction	1.22	(0.89,1.66)	0.215	
Normal, voiding dysfunction, not completed	0.80	(0.44,1.44)	0.455	
Grade of operator				
Consultant	Reference			
Other (Associate specialist, subspec trainee, speciality trainee, other, staff grade, FTSTA)	1.27	(0.95,1.69)	0.106	
Bladder injury	2.28	(1.39,3.75)	0.001	
Univariable analysis (accounting for Centre as a random effect)		Number of imputations	66	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=13225**
Treatment				
RPT	Reference			
PUB	0.20	(0.11,0.39)	<0.001	
AFS	4.84	(2.43,9.65)	<0.001	
Colposuspension	1.44	(0.93,2.25)	0.104	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=12968**
Age (decades)	1.01	(0.93,1.09)	0.815	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=8680**
BMI	1.01	(0.99,1.04)	0.358	

Characteristic	OR	95% CI	pvalue	n=12724
Pre operative urodynamic diagnosis				
USI, USI and voiding dysfunction	Reference			
DOA, Mixed, mixed and voiding dysfunction	1.05	(0.81,1.35)	0.724	
Normal, voiding dysfunction, not completed	0.83	(0.54,1.29)	0.414	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=13099**
Grade of operator				
Consultant	Reference			
Other (Associate specialist, subspec trainee, speciality trainee, other, staff grade, FTSTA)	1.29	(1.02,1.61)	0.030	
Characteristic	**OR**	**95% CI**	**pvalue**	**n=13087**
Bladder injury	2.22	(1.49,3.29)	<0.001	

Tab e *9*: Un var ab e and Mu t var ab e ana ys s readm tted to hosp ta pr mary popu at on

Appendix 8:
Primary population
Secondary analysis: Comparison of patient characteristics within procedures
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RPT	Populations: Non-concomitant First surgery		
Primary outcome:			
PGII			
No change vs Better			
(No change: A tt e better, No change, a tt e worse, much worse, very much worse			
Better: Very much better, much better)			
n=5914			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.83	(0.77,0.90)	<0.001
BMI	0.95	(0.93,0.97)	<0.001
PFMT	1.11	(0.84,1.47)	0.472
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.51	(0.41,0.64)	<0.001
Norma , vo d ng dysfunct on, not comp eted	0.92	(0.60,1.43)	0.718
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.85	(0.68,1.06)	0.146
Bladder injury	0.57	(0.37,0.89)	0.012

Tab e *1*: Pr mary popu at on: RPT: PGII

RPT	Populations: Non-concomitant First surgery		
Secondary outcome:			
Change of SUI			
No change or worse vs Cured or mproved			
n=5748			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.81	(0.72,0.91)	<0.001
BMI	0.96	(0.93,0.99)	0.009
PFMT	1.04	(0.66,1.62)	0.866
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.65	(0.45,0.93)	0.017
Norma , vo d ng dysfunct on, not comp eted	0.96	(0.47,1.94)	0.900
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.72	(0.51,1.03)	0.069
Bladder injury	0.38	(0.21,0.71)	0.002

Tab e *2*: Pr mary popu at on: RPT: SUI

RPT	Populations: Non-concomitant First surgery		
Secondary outcome:			
Change n OAB - of those that had OAB prev ous y....			
No change or worse vs Cured or mproved			
n=3340			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.98	(0.92,1.04)	0.511
BMI	0.99	(0.97,1.00)	0.092
PFMT	0.87	(0.67,1.15)	0.335
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.92	(0.76,1.11)	0.386
Norma , vo d ng dysfunct on, not comp eted	1.43	(0.93,2.20)	0.102
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.88	(0.73,1.07)	0.216
Bladder injury	0.92	(0.60,1.41)	0.696

Tab e *3*: Pr mary popu at on: RPT: pre-op OAB

RPT	Populations: Non-concomitant First surgery		
Secondary outcome:			
Change n OAB - of those who d d not have symptoms prev ous y			
Never present vs New symptoms			
n=2425			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.20	(1.06,1.36)	0.003
BMI	1.01	(0.98,1.04)	0.534
PFMT	1.01	(0.62,1.65)	0.975
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.96	(0.54,1.72)	0.900
Norma , vo d ng dysfunct on, not comp eted	0.86	(0.49,1.53)	0.615
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	1.50	(1.07,2.09)	0.018
Bladder injury	1.18	(0.60,2.31)	0.639

Tab e *4*: Pr mary popu at on: RPT: no pre-op OAB

RPT	Populations: Non-concomitant First surgery		
Secondary outcome:			
B adder njury			
Yes vs No			
n=8493			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.10	(0.99,1.22)	0.081
BMI	0.93	(0.90,0.96)	<0.001
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.75	(0.51,1.10)	0.140
Norma , vo d ng dysfunct on, not comp eted	0.58	(0.31,1.10)	0.095
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	3.88	(2.99,5.05)	<0.001

Tab e *5*: Pr mary popu at on: RPT: B adder njury

RPT	Populations: Non-concomitant First surgery		
Secondary outcome:			
Return to theatre for procedure-re ated event w th n 72 hours			
Yes vs No			
n=6,941			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.90	(0.68,1.19)	0.461
BMI	0.98	(0.91,1.05)	0.530
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.48	(0.17,1.42)	0.185
Norma , vo d ng dysfunct on, not comp eted	1.45	(0.42,5.09)	0.558
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	3.81	(1.96,7.41)	<0.001
Bladder injury	4.23	(1.81,9.90)	0.001

Tab e *6*: Pr mary popu at on: RPT: return to theatre

RPT	Populations: Non-concomitant First surgery		
Secondary outcome:			
Return to hosp ta w th n 30 days for procedure re ated event			
Yes vs No			
n=2,814			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.00	(0.86,1.15)	0.956
BMI	0.99	(0.95,1.03)	0.594
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.85	(0.54,1.33)	0.469
Norma , vo d ng dysfunct on, not comp eted	1.34	(0.70,2.57)	0.378
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	1.25	(0.84,1.86)	0.270
Bladder injury	1.70	(0.85,3.42)	0.134

Tab e *7*: Pr mary popu at on: RPT: return to hosp ta

RPT	Populations: Non-concomitant First surgery		
Secondary outcome:			
Readm tted to hosp ta w th n 30 days for procedure re ated event			
Yes vs No			
n=6,828			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.05	(0.94,1.17)	0.357
BMI	1.00	(0.98,1.03)	0.794
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	1.25	(0.90,1.74)	0.183
Norma , vo d ng dysfunct on, not comp eted	0.84	(0.46,1.55)	0.576
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	1.25	(0.92,1.69)	0.155
Bladder injury	2.10	(1.23,3.58)	0.006

Tab e *8*: Pr mary popu at on: RPT: readm tted to hosp ta

PUB	Populations: Non-concom tant F rst surgery		
Primary outcome:			
PGII			
No change vs Better			
(No change: A tt e better, No change, a tt e worse, much worse, very much worse			
Better: Very much better, much better)			
n=861			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.04	(0.95,1.14)	0.425
BMI	0.98	(0.95,1.02)	0.341
PFMT	1.04	(0.63,1.72)	0.880
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	1.11	(0.78,1.58)	0.572
Norma , vo d ng dysfunct on, not comp eted	0.51	(0.26,0.99)	0.047
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.71	(0.46,1.09)	0.117
Bladder injury	Om tted		

Tab e *9*: Pr mary popu at on: PUB: PGII

PUB	Populations: Non-concom tant F rst surgery		
Secondary outcome:			
Change of SUI			
No change or worse vs Cured or mproved			
n= 838			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.93	(0.83,1.04)	0.180
BMI	0.99	(0.95,1.03)	0.468
PFMT	1.17	(0.66,2.07)	0.599
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	1.02	(0.67,1.56)	0.910
Norma , vo d ng dysfunct on, not comp eted	0.59	(0.29,1.22)	0.156
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.96	(0.57,1.63)	0.890
Bladder injury	Om tted		

Tab e *10*: Pr mary popu at on: PUB:SUI

PUB	**Populations:** Non-concom tant F rst surgery		
Secondary outcome:			
Change n OAB - of those that had OAB prev ous y....			
No change or worse vs Cured or mproved			
n=505			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.01	(0.89,1.15)	0.846
BMI	1.01	(0.97,1.06)	0.665
PFMT	0.98	(0.51,1.90)	0.955
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	1.37	(0.89,2.11)	0.157
Norma , vo d ng dysfunct on, not comp eted	0.91	(0.33,2.48)	0.851
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.58	(0.30,1.13)	0.109
Bladder injury	Om tted		

Tab e *11*: Pr mary popu at on: PUB: pre-OAB

PUB	**Populations:** Non-concom tant F rst surgery		
Secondary outcome:			
Change n OAB - of those who d d not have symptoms prev ous y			
Never present vs New symptoms			
n=319			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 4			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.19	(0.69,2.04)	0.528
BMI	1.11	(0.94,1.30)	0.219
PFMT	331237.20	# Unab e to ca cu ate a CI	0.988
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.00	# Unab e to ca cu ate a CI	0.994
Norma , vo d ng dysfunct on, not comp eted	0.00	# Unab e to ca cu ate a CI	0.996
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	1.52	(0.17,13.81)	0.710
Bladder injury	Om tted		

Tab e *12*: Pr mary popu at on: PUB: no pre-op OAB

PUB	**Populations:** Non-concom tant F rst surgery		
Secondary outcome:			
B adder n ury		ERROR	
Yes vs No			
n=			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)			
BMI			
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on			
DOA, M xed, m xed and vo d ng dysfunct on			
Norma , vo d ng dysfunct on, not comp eted			
Grade of operator			
Consu tant			
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)			
Surgery type			
F rst			
Repeat			

Tab e *13*: Pr mary popu at on: PUB: B adder njury

PUB	**Populations:** Non-concom tant F rst surgery		
Secondary outcome:			
Return to theatre for procedure-re ated event w th n 72 hours		ERROR	
Yes vs No			
n=			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)			
BMI			
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on			
DOA, M xed, m xed and vo d ng dysfunct on			
Norma , vo d ng dysfunct on, not comp eted			
Grade of operator			
Consu tant			
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)			
Bladder injury			
Surgery type			
F rst			
Repeat			

Tab e *14*: Pr mary popu at on: PUB: return to theatre

PUB	Populations: Non-concom tant F rst surgery		
Secondary outcome:			
Return to hosp ta w th n 30 days for procedure re ated event			
Yes vs No			
n=862			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.26	(0.91,1.75)	0.168
BMI	1.04	(0.92,1.17)	0.513
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	2.63	(0.82,8.49)	0.106
Norma , vo d ng dysfunct on, not comp eted	4.02	(1.02,15.90)	0.047
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	3.87	(0.90,16.58)	0.068
Bladder injury	Om tted		

Tab e *15*: Pr mary popu at on: PUB: return to hosp ta

PUB	Populations: Non-concom tant F rst surgery		
Secondary outcome:			
Readm tted to hosp ta w th n 30 days for procedure re ated event			
Yes vs No			
n=961			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.10	(0.65,1.87)	0.723
BMI	0.96	(0.77,1.19)	0.710
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	3.02	(0.60,15.13)	0.180
Norma , vo d ng dysfunct on, not comp eted	0.00	#VALUE! Unab e to ca cu ate CI	0.995
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	7.32	(1.35,39.63)	0.021
Bladder injury	Om tted		

Tab e *16*: Pr mary popu at on: PUB: readm tted to hosp ta

AFS	**Populations:** Non concom tant F rst surgery		
Primary outcome:			
PGII			
No change vs Better			
(No change: A tt e better, No change, a tt e worse, much worse, very much worse			
Better: Very much better, much better)			
n=48			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 31			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.47	(0.10,2.32)	0.354
BMI	0.66	(0.24,1.87)	0.435
PFMT	0.00	# Unab e to ca cu ate CI	0.997
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	1.23	(0.03,52.24)	0.914
Norma , vo d ng dysfunct on, not comp eted	0.09	(0.00,20.21)	0.388
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.01	(0.00,551.52)	0.410
Bladder injury	45400000.00	# Unab e to ca cu ate CI	1.000

Tab e *17*: Pr mary popu at on: AFS: PGII

AFS	**Populations:** Non concom tant F rst surgery		
Secondary outcome:			
Change of SUI			
No change or worse vs Cured or mproved			
n=45			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 3			3
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	2.97	(0.04,214.36)	0.615
BMI	0.60	(0.19,1.92)	0.380
PFMT	0.00	# Unab e to ca cu ate CI	0.998
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	3780000000.00	# Unab e to ca cu ate CI	0.999
Norma , vo d ng dysfunct on, not comp eted	0.07	(0.00,2041.87)	0.616
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.00	(0.00,366.06)	0.287
Bladder injury	973000000.00	# Unab e to ca cu ate CI	0.999

Tab e *18*: Pr mary popu at on: AFS: SUI

AFS	**Populations:** Non concom tant F rst surgery		
Secondary outcome:			
Change n OAB - of those that had OAB prev ous y....			
No change or worse vs Cured or mproved			
n=23			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 19			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	4.93	(0.02,1114.89)	0.564
BMI	1.19	(0.37,3.84)	0.766
PFMT	0.00	# Unab e to ca cu ate CI	0.993
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.05	(0.00,7689.26)	0.617
Norma , vo d ng dysfunct on, not comp eted	0.00	# Unab e to ca cu ate CI	0.996
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	5660000000000000000	# Unab e to ca cu ate CI	0.999
Bladder injury	Om tted		

Tab e *19*: Pr mary popu at on: AFS: Pre-op OAB

AFS	**Populations:** Non concom tant F rst surgery		
Secondary outcome:			
Change n OAB - of those who d d not have symptoms prev ous y			
Never present vs New symptoms			
n=21			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 4			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.14	(0.08,17.08)	0.916
BMI	0.99	(0.75,1.32)	0.965
PFMT	387048.30	# Unab e to ca cu ate CI	0.996
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	8.27	(0.28,247.51)	0.223
Norma , vo d ng dysfunct on, not comp eted	Om tted		
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.00	# Unab e to ca cu ate CI	0.997
Bladder injury	0.28	# Unab e to ca cu ate CI	1.000

Tab e *20*: Pr mary popu at on: AFS: no pre-op OAB

AFS	Populations: Non concom tant F rst surgery		
Secondary outcome:			
B adder n ury			
Yes vs No			
n=91			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 29			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.08	(0.00,4.09)	0.208
BMI	0.88	(0.43,1.80)	0.729
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.00	# Unab e to ca cu ate CI	0.996
Norma , vo d ng dysfunct on, not comp eted	0.00	# Unab e to ca cu ate CI	0.996
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.36	(0.00,1171.97)	0.802

Tab e *21*: Pr mary popu at on: AFS: b adder njury

AFS	Populations: Non concom tant F rst surgery		
Secondary outcome:			
Return to theatre for procedure-re ated event w th n 72 hours			
Yes vs No	**All no for the outcome**		
n=			

Tab e *22*:Pr mary popu at on: AFS: return to theatre

AFS	**Population:** Non concom tant F rst surgery		
Secondary outcome:			
Return to hosp ta w th n 30 days for procedure re ated event			
Yes vs No			
n=53			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 2			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.95	(0.53,1.71)	0.867
BMI	0.85	(0.68,1.07)	0.162
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.41	(0.04,3.96)	0.444
Norma , vo d ng dysfunct on, not comp eted	0.00	# Unab e to ca cu ate CI	0.990
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.00	# Unab e to ca cu ate CI	0.995
Bladder injury	0.16	# Unab e to ca cu ate CI	1.000

Tab e *23*: Pr mary popu at on: AFS: return to hosp ta

AFS	**Populations:** Non concom tant F rst surgery		
Secondary outcome:			
Readm tted to hosp ta w th n 30 days for procedure re ated event			
Yes vs No			
n=58			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 63			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	2.03	(1.10,3.77)	0.024
BMI	1.07	(0.85,1.34)	0.572
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	2.33	(0.39,14.07)	0.356
Norma , vo d ng dysfunct on, not comp eted	2.40	(0.18,31.61)	0.504
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	1.21	(0.08,17.77)	0.888
Bladder injury	0.00	# Unab e to ca cu ate CI	0.996

Tab e *24*: Pr mary popu at on: AFS: readm tted to hosp ta

Colposuspension	**Populations:** Non concom tant F rst surgery pat ents		
Primary outcome:			
PGII			
No change vs Better			
(No change: A tt e better, No change, a tt e worse, much worse, very much worse			
Better: Very much better, much better)			
n=330			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.82	(0.59,1.12)	0.215
BMI	0.98	(0.89,1.08)	0.714
PFMT	1.00	(0.34,2.93)	0.999
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	2.81	(0.81,9.69)	0.102
Norma , vo d ng dysfunct on, not comp eted	780164.50	# Unab e to ca cu ate CI	0.991
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.53	(0.21,1.30)	0.167
Bladder injury	0.56	(0.10,3.04)	0.498

Tab e *25*: Pr mary popu at on: Co posuspens on: PGII

Colposuspension	**Populations:** Non concom tant F rst surgery pat ents		
Secondary outcome:			
Change of SUI			
No change or worse vs Cured or mproved			
n=324			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.47	(0.25,0.87)	0.017
BMI	0.94	(0.76,1.15)	0.536
PFMT	1.13	(0.13,9.93)	0.914
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	7448532.00	# Unab e to ca cu ate CI	0.994
Norma , vo d ng dysfunct on, not comp eted	11000000.00	# Unab e to ca cu ate CI	0.998
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.56	(0.10,3.16)	0.514
Bladder injury	0.40	(0.04,4.10)	0.438

Tab e *26*: Pr mary popu at on: Co posuspens on: SUI

Colposuspension	**Populations:** Non concom tant F rst surgery pat ents		
Secondary outcome:			
Change n OAB - of those that had OAB prev ous y....			
No change or worse vs Cured or mproved			
n=182			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.20	(0.86,1.68)	0.289
BMI	1.01	(0.92,1.11)	0.813
PFMT	0.64	(0.21,2.03)	0.453
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	1.57	(0.70,3.50)	0.274
Norma , vo d ng dysfunct on, not comp eted	4987574.00	# Unab e to ca cu ate CI	0.989
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.57	(0.17,1.96)	0.372
Bladder injury	1.29	(0.18,9.11)	0.799

Tab e *27*: Pr mary popu at on: Co posuspens on: pre-op OAB

Colposuspension	**Populations:** Non concom tant F rst surgery pat ents		
Secondary outcome:			
Change n OAB - of those who d d not have symptoms prev ous y			
Never present vs New symptoms			
n=134			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.89	(0.52,1.51)	0.657
BMI	1.04	(0.89,1.23)	0.599
PFMT	0.88	(0.21,3.69)	0.857
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	2.16	(0.27,17.09)	0.467
Norma , vo d ng dysfunct on, not comp eted	1.93	(0.12,31.03)	0.641
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	1.45	(0.35,5.98)	0.606
Bladder injury	4.93	(0.24,102.60)	0.303

Tab e *28*: Pr mary popu at on: Co posuspens on: no pre-op OAB

Colposuspension	**Populations:** Non concom tant F rst surgery pat ents		
Secondary outcome:			
B adder n ury			
Yes vs No			
n=451			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.67	(1.03,2.71)	0.036
BMI	1.01	(0.89,1.15)	0.867
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	1.64	(0.43,6.23)	0.465
Norma , vo d ng dysfunct on, not comp eted	0.00	# Unab e to ca cu ate CI	0.993
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	1.00	(0.21,4.74)	0.998

Tab e *29*: Pr mary popu at on: Co posuspens on: b adder njury

Colposuspension	**Populations:** Non concom tant F rst surgery pat ents		
Secondary outcome:			
Return to theatre for procedure-re ated event w th n 72 hours			
Yes vs No			
n=365			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 44			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.26	(0.13,12.07)	0.843
BMI	1.01	(0.41,2.46)	0.984
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.00	# Unab e to ca cu ate CI	0.994
Norma , vo d ng dysfunct on, not comp eted	0.00	# Unab e to ca cu ate CI	0.998
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.00	# Unab e to ca cu ate CI	0.994
Bladder injury	0.00	# Unab e to ca cu ate CI	0.998

Tab e *30*: Pr mary popu at on: Co posuspens on: return to theatre

Colposuspension	**Populations:** Non concom tant F rst surgery pat ents		
Secondary outcome:			
Return to hosp ta w th n 30 days for procedure re ated event			
Yes vs No			
n=303			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	2.03	(1.31,3.16)	0.002
BMI	0.96	(0.84,1.10)	0.575
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.50	(0.10,2.46)	0.394
Norma , vo d ng dysfunct on, not comp eted	0.00	#VALUE! Unab e to ca cu ate CI	0.993
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.57	(0.10,3.11)	0.517
Bladder injury	1.56	(0.15,16.09)	0.711

Tab e *31*: Pr mary popu at on: Co posuspens on: return hosp ta

Colposuspension	**Populations:** Non concom tant F rst surgery pat ents		
Secondary outcome:			
Readm tted to hosp ta w th n 30 days for procedure re ated event			
Yes vs No			
n=360			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 65			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.82	(1.12,2.95)	0.016
BMI	1.10	(0.96,1.26)	0.163
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.27	(0.03,2.37)	0.235
Norma , vo d ng dysfunct on, not comp eted	0.00	#VALUE! Unab e to ca cu ate CI	0.994
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.48	(0.08,2.78)	0.411
Bladder injury	10.20	(1.56,66.76)	0.015

Tab e *32*: Pr mary popu at on: Co posuspens on: readm t hosp ta

Appendix 9:
Secondary population:
Baseline characteristics, patient reported outcomes and complications

Tables

Table 1: Patient and surgical characteristics of RPT, PUB, AFS and colposuspension for the secondary population 3
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Baseline characteristics: Secondary population 'All patients'

Treatment	**RPT**	**PUB**	**AFS**	**Colposuspension**
N=31901	n=24923	n=4740	n=538	n=1700
Age (years), mean (SD)	52.54 (11.79)	57.00 (15.64)	51.90 (11.14)	50.66 (11.09)
m ss ng, n(%)	701(2.8)	207(4.4)	24(4.5)	110(6.5)
Age categories, n(%)				
Age ess than 50	11236 (45.1)	1606 (33.9)	230 (42.8)	784 (46.1)
Age between 50-79	12573 (50.4)	2527 (53.3)	280 (52.0)	789 (46.4)
Age 80 and over	413 (1.7)	400 (8.4)	4 (0.7)	17 (1.0)
M ss ng	701 (2.8)	207 (4.4)	24 (4.5)	110 (6.5)
BMI, mean (SD)	28.53 (4.89)	29.25 (5.42)	28.73 (4.81)	28.63 (4.73)
m ss ng, n(%)	13330(53.5)	3292(69.5)	377(70.1)	936(55.1)
BMI categories				
Underwe ght	23 (0.1)	3 (0.1)	0 (0.0)	0 (0.0)
Hea thy we ght	3029 (12.2)	350 (7.4)	35 (6.5)	198 (11.6)
Overwe ght - ower	4479 (18.0)	508 (10.7)	69 (12.8)	285 (16.8)
Overwe ght - upper	2771 (11.1)	355 (7.5)	40 (7.4)	197 (11.6)
Obese	1291 (5.2)	232 (4.9)	17 (3.2)	84 (4.9)
M ss ng	13330 (53.5)	3292 (69.5)	377 (70.1)	936 (55.1)
Pelvic floor exercises offered, n(%)				
Yes and accepted	19122 (76.7)	3349 (70.7)	371 (69.0)	1262 (74.2)
Yes but dec ned	761 (3.1)	111 (2.3)	29 (5.4)	53 (3.1)
No	1955 (7.8)	416 (8.8)	54 (10.0)	190 (11.2)
M ss ng	3085 (12.4)	864 (18.2)	84 (15.6)	195 (11.5)
Pelvic floor exercises, n(%)				
Yes	19122 (76.7)	3349 (70.7)	371 (69.0)	1262 (74.2)
No	2716 (10.9)	527 (11.1)	83 (15.4)	243 (14.3)
M ss ng	3085 (12.4)	864 (18.2)	84 (15.6)	195 (11.5)
Grade of operator, n(%)				
Consu tant	19290 (77.4)	4012 (84.6)	409 (76.0)	1405 (82.6)
Assoc ate Spec a st	143 (0.6)	5 (0.1)	1 (0.2)	4 (0.2)
Subspec Tra nee (SST)	1452 (5.8)	204 (4.3)	85 (15.8)	186 (10.9)
Spec a ty Tra nee (ST)	3160 (12.7)	274 (5.8)	22 (4.1)	67 (3.9)
Staff grade	230 (0.9)	53 (1.1)	1 (0.2)	3 (0.2)
FTSTA	8 (<1)	0 (0.0)	0 (0.0)	1 (0.1)
Other	236 (0.9)	8 (0.2)	0 (0.0)	5 (0.3)
M ss ng	404 (1.6)	184 (3.9)	20 (3.7)	29 (1.7)
Grade of operator, n(%)				
Consu tant	19290 (77.4)	4012 (84.6)	409 (76.0)	1405 (82.6)
Other	5229 (21.0)	544 (11.5)	109 (20.3)	266 (15.6)
M ss ng	404 (1.6)	184 (3.9)	20 (3.7)	29 (1.7)

Pre-op urodynamic diagnosis, n(%)				
USI	17506 (70.2)	2808 (59.2)	346 (64.3)	1240 (72.9)
USI + vo d ng dysfunct	605 (2.4)	115 (2.4)	12 (2.2)	38 (2.2)
Norma	560 (2.2)	99 (2.1)	3 (0.6)	20 (1.2)
M xed	3494 (14.0)	681 (14.4)	80 (14.9)	159 (9.4)
M xed + vo d ng dysfunc	133 (0.5)	24 (0.5)	3 (0.6)	9 (0.5)
DOA	104 (0.4)	33 (0.7)	2 (0.4)	3 (0.2)
Vo d ng dysfunct on	11 (<1)	9 (0.2)	0 (0.0)	2 (0.1)
Not comp eted	665 (2.7)	203 (4.3)	16 (3.0)	34 (2.0)
M ss ng	1845 (7.4)	768 (16.2)	76 (14.1)	195 (11.5)
Pre-op urodynamic diagnosis, n(%)				
USI, USI+Vo d Dysfunct on	18111 (72.7)	2923 (61.7)	358 (66.5)	1278 (75.2)
DOA, M x, M xed+vo d dys	3731 (15.0)	738 (15.6)	85 (15.8)	171 (10.1)
Norma , vo d dysf, not done	1236 (5.0)	311 (6.6)	19 (3.5)	56 (3.3)
M ss ng	1845 (7.4)	768 (16.2)	76 (14.1)	195 (11.5)
Incontinence Surgery Type, n(%)				
Pr mary	22742 (91.2)	3220 (67.9)	285 (53.0)	1248 (73.4)
Repeat	1411 (5.7)	1160 (24.5)	214 (39.8)	336 (19.8)
M ss ng	770 (3.1)	360 (7.6)	39 (7.2)	116 (6.8)

Table 1: Patient and surgical characteristics of RPT, PUB, AFS and colposuspension for the secondary population

1

Treatment N=31901	RPT		PUB		AFS		Colposuspension		Total patients
	n=24923		n=4740		n=538		n=1700		
Population: Secondary: All patients									
PGII, n(%)									
Better	14495	90.5%	1414	55.3%	207	90.4%	810	85.5%	
Not better	1527	9.5%	1144	44.7%	22	9.6%	137	14.5%	
Total	16022		2558		229		947		19756
Missing PGII	8901		2182		309		753		
SUI, n(%)									
Cured or Improved	14231	96.4%	1667	71.9%	207	97.2%	832	94.0%	
No change or Worse	529	3.6%	653	28.1%	6	2.8%	53	6.0%	
Total	14760		2320		213		885		18,178
Missing SUI	10163		2420		325		815		
OAB (Patients that had symptoms previously, n=25100), n(%)									
Cured or Improved	5606	63.1%	529	38.1%	46	34.6%	230	45.8%	
No change or Worse	3280	36.9%	861	61.9%	87	65.4%	272	54.2%	
Total	8886		1390		133		502		10,911
OAB (Patients did not have symptoms previously, n=20998), n(%)									
New symptoms	542	9.6%	22	3.0%	9	13.0%	49	13.8%	
Never present	5119	90.4%	703	97.0%	60	87.0%	305	86.2%	
Total	5661		725		69		354		6,809
Missing OAB	10376		2625		336		844		

2 *Table 2 Patient reported outcomes following RPT, PUB, AFS and colposuspension: Secondary*
3 *population: All patients*

Assessment across treatments: Secondary population 'All patients'
Crude odds ratio with unadjusted data

Outcome measure	**OR (95% CI)**	**p value**
PGII n=19,756		
RPT	Reference	
PUB	0.13 (0.12,0.14)	<0.001
AFS	0.99 (0.64,1.54)	0.969
Co posuspens on	0.62 (0.52,0.75)	<0.001
Constant	9.49 (9.00,10.01)	
SUI symptoms n=18,178		
RPT	Reference	
PUB	0.09 (0.08,0.11)	<0.001
AFS	1.28 (0.57,2.90)	0.55
Co posuspens on	0.58 (0.44,0.78)	<0.001
Constant	26.90 (24.67,29.34)	
OAB (Patients with pre-operative symptoms n=10,911		
RPT	Reference	
PUB	0.36 (0.32,0.40)	<0.001
AFS	0.31 (0.22,0.44)	<0.001
Co posuspens on	0.49 (0.41,0.59)	<0.001
Constant	1.71 (1.64,1.78)	
OAB (Patients without pre-operative symptoms n=6,809		
RPT	Reference	
PUB	0.30 (0.19,0.46)	<0.001
AFS	1.42 (0.70,2.87)	0.334
Co posuspens on	1.52 (1.11,2.08)	0.009
Constant	0.11 (0.10,0.12)	

Table *3*: Unadjusted odds ratios: for *outcomes following RPT, PUB, AFS and colposuspension: Secondary population: All patients*

Complications: Secondary population: ‘All patients’

Treatment	RPT	PUB	AFS	Co posuspens on
N=31901	n=24923	n=4740	n=538	n=1700
Intra-operative bladder injury, n(%)				
Yes	890 (3.6)	3 (0.1)	22 (4.1)	52 (3.1)
No	23638 (94.8)	4666 (98.4)	500 (92.9)	1620 (95.3)
Missing	395 (1.6)	71 (1.5)	16 (3.0)	28 (1.6)
Return to theatre for procedure-related event within 72 hours				
Yes	110 (0.4)	2 (<1)	2 (0.4)	12 (0.7)
No	17989 (72.2)	2826 (59.6)	258 (48.0)	1075 (63.2)
M ss ng	6824 (27.4)	1912 (40.3)	278 (51.7)	613 (36.1)
Return to hospital within 30 days for procedure related event				
Yes	391 (1.6)	47 (1.0)	38 (7.1)	78 (4.6)
No	4756 (19.1)	2167 (45.7)	172 (32.0)	677 (39.8)
M ss ng	19776 (79.3)	2526 (53.3)	328 (61.0)	945 (55.6)
Readmitted to hospital within 30 days for procedure related event				
Yes	773 (3.1)	25 (0.5)	23 (4.3)	69 (4.1)
No	16997 (68.2)	2762 (58.3)	233 (43.3)	992 (58.4)
M ss ng	7153 (28.7)	1953 (41.2)	282 (52.4)	639 (37.6)

Table 4: Complications following RPT, PUB, AFS and colposuspension: Secondary population: All patients

Appendix 10:
Secondary population
Secondary analysis: Comparison of patient characteristics within procedures
Multivariable analysis

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RPT	Populations: All patients		
Primary outcome:			
PGII			
No change vs Better			
(No change: A tt e better, No change, a tt e worse, much worse, very much worse			
Better: Very much better, much better)			
n=6,796			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 0 The comb nat on of var ab es and outcome d d not use mputed data, therefore resu ts are based on non- mputed data (.e. or g na data) Error code: No mputat ons to ca cu ate the between mputat on var ance			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.83	(0.78,0.89)	<0.001
BMI	0.95	(0.94,0.97)	<0.001
PFMT	1.06	(0.86,1.32)	0.572
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.52	(0.42,0.63)	<0.001
Norma , vo d ng dysfunct on, not comp eted	0.96	(0.65,1.42)	0.834
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.91	(0.74,1.11)	0.345
Bladder injury	0.61	(0.41,0.92)	0.018
Surgery type			
F rst	Reference		
Repeat	0.68	(0.51,0.92)	0.012

Tab e *1*:Secondary popu at on: RPT: PGII

RPT	Populations: All patients		
Secondary outcome:			
Change of SUI			
No change or worse vs Cured or improved			
n=6,633			
Multivariable analysis (accounting for Centre as a random effect)			
Number of imputations = 0 The combination of variables and outcome did not use imputed data, therefore results are based on non-imputed data (i.e. original data) Error code: No imputations to calculate the between imputation variance			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.76	(0.68,0.84)	<0.001
BMI	0.95	(0.93,0.98)	<0.001
PFMT	0.79	(0.56,1.12)	0.185
Pre operative urodynamic diagnosis			
USI, USI and voiding dysfunction	Reference		
DOA, Mixed, mixed and voiding dysfunction	0.64	(0.47,0.87)	0.004
Normal, voiding dysfunction, not completed	1.04	(0.55,1.98)	0.893
Grade of operator			
Consultant	Reference		
Other (Associate specialist, subspecialty trainee, specialty trainee, other, staff grade, FTSTA)	0.95	(0.68,1.33)	0.753
Bladder injury	0.47	(0.26,0.87)	0.015
Surgery type			
First	Reference		
Repeat	0.55	(0.36,0.83)	0.004

Table 2: Secondary population: RPT: SUI

RPT	Populations: All patients		
Secondary outcome:			
Change n OAB - of those that had OAB prev ous y....			
No change or worse vs Cured or mproved			
n=3,891			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 0 The comb nat on of var ab es and outcome d d not use mputed data, therefore resu ts are based on non- mputed data (.e. or g na data) Error code: No mputat ons to ca cu ate the between mputat on var ance			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.02	(0.96,1.09)	0.451
BMI	0.99	(0.97,1.00)	0.059
PFMT	0.92	(0.75,1.12)	0.391
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.91	(0.76,1.09)	0.288
Norma , vo d ng dysfunct on, not comp eted	0.93	(0.64,1.35)	0.710
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	1.02	(0.85,1.22)	0.856
Bladder injury	1.00	(0.67,1.49)	0.984
Surgery type			
F rst	Reference		
Repeat	0.90	(0.68,1.20)	0.474

Tab e *3*: Secondary popu at on: RPT: pre-op OAB

RPT	Populations: All patients		
Secondary outcome:			
Change n OAB - of those who d d not have symptoms prev ous y			
Never present vs New symptoms			
n=2,692			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 0 The comb nat on of var ab es and outcome d d not use mputed data, therefore resu ts are based on non- mputed data (.e. or g na data) Error code: No mputat ons to ca cu ate the between mputat on var ance			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.20	(1.07,1.34)	0.002
BMI	1.01	(0.98,1.04)	0.549
PFMT	1.06	(0.70,1.61)	0.775
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.88	(0.51,1.50)	0.635
Norma , vo d ng dysfunct on, not comp eted	0.96	(0.57,1.61)	0.874
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	1.49	(1.09,2.05)	0.013
Bladder injury	1.27	(0.65,2.48)	0.486
Surgery type			
F rst	Reference		
Repeat	0.68	(0.33,1.38)	0.285

Tab e *4*: Secondary popu at on: RPT: no pre-op OAB

RPT	Populations: All patients		
Secondary outcome:			
B adder njury			
Yes vs No			
n=12,558			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.06	(0.97,1.15)	0.230
BMI	0.92	(0.90,0.95)	<0.001
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.84	(0.61,1.15)	0.266
Norma , vo d ng dysfunct on, not comp eted	0.62	(0.36,1.07)	0.084
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	4.00	(3.20,5.00)	<0.001
Surgery type			
F rst	Reference		
Repeat	1.67	(1.10,2.53)	0.016

Tab e *5*: Secondary popu at on: RPT: b adder njury

RPT	Populations: All patients		
Secondary outcome:			
Return to theatre for procedure-re ated event w th n 72 hours			
Yes vs No			
n=10,271			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.91	(0.73,1.13)	0.376
BMI	0.97	(0.92,1.03)	0.316
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.75	(0.36,1.55)	0.432
Norma , vo d ng dysfunct on, not comp eted	0.89	(0.27,2.95)	0.844
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	3.19	(1.89,5.40)	<0.001
Bladder injury	3.03	(1.42,6.48)	0.004
Surgery type			
F rst	Reference		
Repeat	0.32	(0.04,2.33)	0.260

Tab e *6*: Secondary popu at on: RPT: Return to theatre

RPT	Populations: All patients		
Secondary outcome:			
Return to hosp ta w th n 30 days for procedure re ated event			
Yes vs No			
n=4,060			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.02	(0.92,1.13)	0.727
BMI	1.00	(0.97,1.04)	0.826
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.89	(0.62,1.26)	0.495
Norma , vo d ng dysfunct on, not comp eted	1.43	(0.87,2.35)	0.163
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	1.23	(0.89,1.68)	0.206
Bladder injury	1.73	(1.00,2.98)	0.049
Surgery type			
F rst	Reference		
Repeat	1.07	(0.60,1.90)	0.817

Tab e *7*: Secondary popu at on: RPT: Return to hosp ta

RPT	Populations: All patients		
Secondary outcome:			
Readm tted to hosp ta w th n 30 days for procedure re ated event			
Yes vs No			
n=10,113			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.07	(0.98,1.16)	0.125
BMI	0.99	(0.97,1.01)	0.501
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	1.26	(0.97,1.63)	0.086
Norma , vo d ng dysfunct on, not comp eted	1.08	(0.70,1.66)	0.743
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	1.27	(1.00,1.62)	0.050
Bladder injury	1.79	(1.16,2.78)	0.009
Surgery type			
F rst	Reference		
Repeat	0.97	(0.63,1.50)	0.902

Tab e *8*: Secondary popu at on: RPT: readm tted to hosp ta

PUB	**Populations:** A pat ents		
Primary outcome:			
PGII			
No change vs Better			
(No change: A tt e better, No change, a tt e worse, much worse, very much worse			
Better: Very much better, much better)			
n=676			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 0 The comb nat on of var ab es and outcome d d not use mputed data, therefore resu ts are based on non- mputed data (.e. or g na data) Error code: No mputat ons to ca cu ate the between mputat on var ance			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.02	(0.92,1.14)	0.671
BMI	1.01	(0.98,1.04)	0.495
PFMT	1.11	(0.67,1.83)	0.696
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.95	(0.63,1.42)	0.791
Norma , vo d ng dysfunct on, not comp eted	0.53	(0.26,1.07)	0.077
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	1.00	(0.59,1.69)	0.995
Bladder injury	Om tted		
Surgery type			
F rst	Reference		
Repeat	0.66	(0.45,0.96)	0.031

Tab e *9*: Secondary popu at on: PUB:PGI

PUB	**Populations:** A pat ents		
Secondary outcome:			
Change of SUI			
No change or worse vs Cured or mproved			
n=624			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 0 The comb nat on of var ab es and outcome d d not use mputed data, therefore resu ts are based on non- mputed data (.e. or g na data) Error code: No mputat ons to ca cu ate the between mputat on var ance			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.99	(0.87,1.13)	0.892
BMI	1.01	(0.98,1.05)	0.454
PFMT	1.46	(0.82,2.59)	0.200
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.73	(0.46,1.17)	0.188
Norma , vo d ng dysfunct on, not comp eted	0.58	(0.27,1.28)	0.180
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	1.14	(0.60,2.18)	0.691
Bladder injury	Om tted		
Surgery type			
F rst	Reference		
Repeat	0.58	(0.37,0.91)	0.018

Tab e *10*: Secondary popu at on: PUB:SUI

PUB	**Populations:** A pat ents		
Secondary outcome:			
Change n OAB - of those that had OAB prev ous y....			
No change or worse vs Cured or mproved			
N = 395			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 0 The comb nat on of var ab es and outcome d d not use mputed data, therefore resu ts are based on non- mputed data (.e. or g na data) Error code: No mputat ons to ca cu ate the between mputat on var ance			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.97	(0.84,1.11)	0.621
BMI	1.03	(0.99,1.07)	0.137
PFMT	1.01	(0.52,1.94)	0.986
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	1.11	(0.70,1.76)	0.653
Norma , vo d ng dysfunct on, not comp eted	1.41	(0.58,3.43)	0.454
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.49	(0.23,1.03)	0.061
Bladder injury	Om tted		
Surgery type			
F rst	Reference		
Repeat	0.44	(0.26,0.74)	0.002

Tab e *11*: Secondary popu at on: PUB: pre-op OAB

PUB	**Populations:** A pat ents		
Secondary outcome:			
Change n OAB - of those who d d not have symptoms prev ous y			
Never present vs New symptoms	**ERROR**		
n =			
Multivariable analysis (accounting for Centre as a random effect)		Number of mputat ons	
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.00	(0.00,0.00)	<0.001
BMI	0.00	(0.00,0.00)	<0.001
PFMT	0.00	(0.00,0.00)	<0.001
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.00	(0.00,0.00)	<0.001
Norma , vo d ng dysfunct on, not comp eted	0.00	(0.00,0.00)	<0.001
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.00	(0.00,0.00)	<0.001
Bladder injury	0.00	(0.00,0.00)	<0.001
Surgery type			
F rst	Reference		
Repeat	0.00	(0.00,0.00)	<0.001

Tab e *12*: Secondary popu at on: PUB: No pre-op OAB

PUB	**Populations:** A pat ents		
Secondary outcome:			
B adder njury	**ERROR**		
Yes vs No			
n=			
Multivariable analysis (accounting for Centre as a random effect)		Number of mputat ons	
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.00	(0.00,0.00)	<0.001
BMI	0.00	(0.00,0.00)	<0.001
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.00	(0.00,0.00)	<0.001
Norma , vo d ng dysfunct on, not comp eted	0.00	(0.00,0.00)	<0.001
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.00	(0.00,0.00)	<0.001
Surgery type			
F rst	Reference		
Repeat	0.00	(0.00,0.00)	<0.001

Tab e *13*: Secondary popu at on: PUB: b adder njury

PUB	**Populations:** A pat ents		
Secondary outcome:			
Return to theatre for procedure-re ated event w th n 72 hours			
Yes vs No			
n= 1,665			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 19			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	3.49	(0.21,57.40)	0.382
BMI	1.00	(0.39,2.57)	0.995
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	1794827.00	# Unab e to ca cu ate a CI	0.993
Norma , vo d ng dysfunct on, not comp eted	0.13	# Unab e to ca cu ate a CI	1.000
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.00	# Unab e to ca cu ate a CI	0.995
Bladder injury	Om tted		
Surgery type			
F rst	Reference		
Repeat	0.00	# Unab e to ca cu ate a CI	0.994

Tab e *14* Secondary popu at on: PUB: Return to theatre

PUB	**Populations:** A pat ents		
Secondary outcome:			
Return to hosp ta w th n 30 days for procedure re ated event			
Yes vs No			
n=1,433			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.08	(0.85,1.37)	0.553
BMI	0.99	(0.91,1.08)	0.906
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	1.53	(0.64,3.69)	0.339
Norma , vo d ng dysfunct on, not comp eted	2.06	(0.69,6.15)	0.195
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	1.96	(0.70,5.47)	0.200
Bladder injury	Om tted		
Surgery type			
F rst	Reference		
Repeat	0.66	(0.24,1.80)	0.416

Tab e *15*: Secondary popu at on: PUB: Return to hosp ta

PUB	**Populations:** A pat ents		
Secondary outcome:			
Readm tted to hosp ta w th n 30 days for procedure re ated event			
Yes vs No			
n=1,646			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 65			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.25	(1.76,0.00)	0.746
BMI	0.94	(0.79,1.13)	0.519
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	2.52	(0.69,9.19)	0.162
Norma , vo d ng dysfunct on, not comp eted	0.00	#VALUE! Unab e to ca cu ate a CI	0.994
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	3.53	(0.89,13.95)	0.072
Bladder injury	Om tted		
Surgery type			
F rst	Reference		
Repeat	1.54	(0.39,6.08)	0.538

Tab e *16*: Secondary popu at on: PUB: readm tted to hosp ta

AFS	**Populations:** A pat ents		
Primary outcome:			
PGII			
No change vs Better			
(No change: A tt e better, No change, a tt e worse, much worse, very much worse			
Better: Very much better, much better)			
n=54			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 0 The comb nat on of var ab es and outcome d d not use mputed data, therefore resu ts are based on non- mputed data (.e. or g na data) Error code: No mputat ons to ca cu ate the between mputat on var ance			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.25	(0.38,4.07)	0.711
BMI	0.78	(0.59,1.02)	0.072
PFMT	0.41	(0.02,9.63)	0.577
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	8155642.00	#VALUE! Unab e to ca cu ate a CI	0.995
Norma , vo d ng dysfunct on, not comp eted	0.27	(0.01,6.59)	0.423
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.12	(0.00,3.26)	0.205
Bladder injury	0.05	(0.00,2.60)	0.137
Surgery type			
F rst	Reference		
Repeat	0.37	(0.03,4.84)	0.451

Tab e *17*: Secondary popu at on: AFS: PGII

AFS	**Populations:** A pat ents		
Secondary outcome:			
Change of SUI			
No change or worse vs Cured or mproved			
n=50			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 0 The comb nat on of var ab es and outcome d d not use mputed data, therefore resu ts are based on non- mputed data (.e. or g na data) Error code: No mputat ons to ca cu ate the between mputat on var ance			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.70	(0.16,2.94)	0.622
BMI	0.69	(0.44,1.09)	0.112
PFMT	0.00	#VALUE! Unab e to ca cu ate a CI	0.995
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	182000000.00	#VALUE! Unab e to ca cu ate a CI	0.998
Norma , vo d ng dysfunct on, not comp eted	0.23	(0.00,10.93)	0.456
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.01	(0.00,2.56)	0.100
Bladder injury	245000000.00	#VALUE! Unab e to ca cu ate a CI	0.999
Surgery type			
F rst	Reference		
Repeat	0.31	(0.01,7.64)	0.476

Tab e *18*: Secondary popu at on: AFS: SUI

AFS	**Populations:** A pat ents		
Secondary outcome:			
Change n OAB - of those that had OAB prev ous y....			
No change or worse vs Cured or mproved			
n=28			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 0 The comb nat on of var ab es and outcome d d not use mputed data, therefore resu ts are based on non- mputed data (.e. or g na data) Error code: No mputat ons to ca cu ate the between mputat on var ance			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.74	(0.29,10.58)	0.546
BMI	0.90	(0.67,1.21)	0.471
PFMT	0.47	(0.01,16.15)	0.674
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.69	(0.03,15.95)	0.817
Norma , vo d ng dysfunct on, not comp eted	12.44	(0.21,727.75)	0.225
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	3.18	(0.02,446.24)	0.646
Bladder injury	26800000.00	#VALUE! Unab e to ca cu ate a CI	0.995
Surgery type			
F rst	Reference		
Repeat	2.27	(0.09,55.45)	0.614

Tab e *19*: Secondary popu at on: AFS: pre-op OAB

AFS	**Populations:** A pat ents		
Secondary outcome:			
Change n OAB - of those who d d not have symptoms prev ous y			
Never present vs New symptoms			
n=	**ERROR**		
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.00	(0.00,0.00)	<0.001
BMI	0.00	(0.00,0.00)	<0.001
PFMT	0.00	(0.00,0.00)	<0.001
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.00	(0.00,0.00)	<0.001
Norma , vo d ng dysfunct on, not comp eted	0.00	(0.00,0.00)	<0.001
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.00	(0.00,0.00)	<0.001
Bladder injury	0.00	(0.00,0.00)	<0.001
Surgery type			
F rst	Reference		
Repeat	0.00	(0.00,0.00)	<0.001

Tab e *20*: Secondary popu at on: AFS: No pre-op OAB

AFS	**Populations:** A pat ents		
Secondary outcome:			
B adder njury			
Yes vs No			
n=233			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 50			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.98	(0.56,1.73)	0.942
BMI	0.90	(0.75,1.09)	0.300
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.00	# Unab e to ca cu ate a CI	0.993
Norma , vo d ng dysfunct on, not comp eted	0.00	# Unab e to ca cu ate a CI	0.995
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	1.77	(0.30,10.60)	0.533
Surgery type			
F rst	Reference		
Repeat	2.01	(0.40,10.04)	0.394

Tab e *21*: Secondary popu at on: AFS: b adder njury

AFS	**Populations:** A pat ents		
Secondary outcome:			
Return to theatre for procedure-re ated event w th n 72 hours			
Yes vs No			
n=159			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 4			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.14	(0.00,455.36)	0.635
BMI	0.31	(0.00,43.82)	0.639
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.00	#! Unab e to ca cu ate a CI	0.996
Norma , vo d ng dysfunct on, not comp eted	0.00	#! Unab e to ca cu ate a CI	0.998
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.00	#! Unab e to ca cu ate a CI	0.995
Bladder injury	0.00	#! Unab e to ca cu ate a CI	0.999
Surgery type			
F rst	Reference		
Repeat	355329.40	#! Unab e to ca cu ate a CI	0.988

Tab e *22*: Secondary popu at on: AFS: Return to theatre

AFS	**Populations:** A pat ents		
Secondary outcome:			
Return to hosp ta w th n 30 days for procedure re ated event			
Yes vs No			
n=140			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.01	(0.65,1.55)	0.982
BMI	0.95	(0.84,1.08)	0.449
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	1.22	(0.39,3.84)	0.733
Norma , vo d ng dysfunct on, not comp eted	0.65	(0.07,5.71)	0.695
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.36	(0.07,1.77)	0.209
Bladder injury	6.06	(0.66,55.56)	0.111
Surgery type			
F rst	Reference		
Repeat	0.98	(0.38,2.54)	0.962

Tab e *23*: Secondary popu at on: AFS: Return to hosp ta

AFS	**Populations:** A pat ents		
Secondary outcome:			
Readm tted to hosp ta w th n 30 days for procedure re ated event			
Yes vs No			
n=159			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.55	(1.00,2.40)	0.048
BMI	1.02	(0.89,1.17)	0.790
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	1.98	(0.58,6.81)	0.276
Norma , vo d ng dysfunct on, not comp eted	1.32	(0.14,12.23)	0.806
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.64	(0.13,3.25)	0.595
Bladder injury	4.74	(0.38,59.90)	0.229
Surgery type			
F rst	Reference		
Repeat	0.35	(0.10,1.16)	0.086

Tab e *24*: Secondary popu at on: AFS: Readm tted to hosp ta

Colposuspension	**Populations:** A pat ents		
Primary outcome:			
PGII			
No change vs Better			
(No change: A tt e better, No change, a tt e worse, much worse, very much worse			
Better: Very much better, much better)			
n=377			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 0 The comb nat on of var ab es and outcome d d not use mputed data, therefore resu ts are based on non- mputed data (.e. or g na data) Error code: No mputat ons to ca cu ate the between mputat on var ance			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.83	(0.63,1.09)	0.176
BMI	1.01	(0.95,1.09)	0.697
PFMT	1.11	(0.49,2.50)	0.810
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	1.19	(0.43,3.29)	0.739
Norma , vo d ng dysfunct on, not comp eted	0.88	(0.09,8.58)	0.910
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	1.22	(0.44,3.39)	0.707
Bladder injury	0.63	(0.12,3.28)	0.580
Surgery type			
F rst	Reference		
Repeat	0.43	(0.22,0.86)	0.016

Tab e *25*: Secondary popu at on: Co posuspens on: PGII

Colposuspension	**Populations:** A pat ents		
Secondary outcome:			
Change of SUI			
No change or worse vs Cured or mproved			
n=360			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 0 The comb nat on of var ab es and outcome d d not use mputed data, therefore resu ts are based on non- mputed data (.e. or g na data) Error code: No mputat ons to ca cu ate the between mputat on var ance			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.70	(0.46,1.07)	0.102
BMI	1.00	(0.90,1.11)	0.938
PFMT	0.70	(0.18,2.77)	0.617
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.49	(0.12,1.97)	0.318
Norma , vo d ng dysfunct on, not comp eted	0.20	(0.02,2.07)	0.177
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.31	(0.09,1.12)	0.074
Bladder injury	600843.00	#VALUE! Unab e to ca cu ate CI	0.991
Surgery type			
F rst	Reference		
Repeat	0.23	(0.08,0.66)	0.006

Tab e *26*: Secondary popu at on: Co posuspens on: SUI

Colposuspension	**Populations:** A pat ents		
Secondary outcome:			
Change n OAB - of those that had OAB prev ous y....			
No change or worse vs Cured or mproved			
n=188			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 0 The comb nat on of var ab es and outcome d d not use mputed data, therefore resu ts are based on non- mputed data (.e. or g na data) Error code: No mputat ons to ca cu ate the between mputat on var ance			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.31	(0.96,1.78)	0.092
BMI	0.99	(0.93,1.06)	0.808
PFMT	0.70	(0.29,1.72)	0.441
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.85	(0.37,1.92)	0.691
Norma , vo d ng dysfunct on, not comp eted	1.77	(0.25,12.53)	0.570
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	1.00	(0.32,3.15)	0.998
Bladder injury	0.98	(0.16,6.02)	0.985
Surgery type			
F rst	Reference		
Repeat	0.69	(0.31,1.52)	0.356

Tab e *27*: Secondary popu at on: Co posuspens on: pre-op OAB

Colposuspension	**Populations:** A pat ents		
Secondary outcome:	**ERROR**		
Change n OAB - of those who d d not have symptoms prev ous y			
Never present vs New symptoms			
n=			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.00	(0.00,0.00)	<0.001
BMI	0.00	(0.00,0.00)	<0.001
PFMT	0.00	(0.00,0.00)	<0.001
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.00	(0.00,0.00)	<0.001
Norma , vo d ng dysfunct on, not comp eted	0.00	(0.00,0.00)	<0.001
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.00	(0.00,0.00)	<0.001
Bladder injury	0.00	(0.00,0.00)	<0.001
Surgery type			
F rst	Reference		
Repeat	0.00	(0.00,0.00)	<0.001

Tab e *28*: Secondary popu at on: Co posuspens on: no pre-op OAB

Colposuspension	**Populations:** A pat ents		
Secondary outcome:			
B adder n ury			
Yes vs No			
n=906			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 65			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.32	(0.96,1.83)	0.092
BMI	1.01	(0.92,1.11)	0.810
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.92	(0.27,3.21)	0.902
Norma , vo d ng dysfunct on, not comp eted	0.00	# Unab e to ca cu ate a CI	0.992
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.88	(0.25,3.10)	0.838
Surgery type			
F rst	Reference		
Repeat	1.49	(0.58,3.82)	0.404

Tab e *29*: Secondary popu at on: Co posuspens on: B adder njury

Colposuspension	**Populations:** A pat ents		
Secondary outcome:			
Return to theatre for procedure-re ated event w th n 72 hours			
Yes vs No			
n=738			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 26			
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	0.67	(0.25,1.80)	0.429
BMI	1.00	(0.72,1.38)	0.982
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.00	# Unab e to ca cu ate a CI	0.990
Norma , vo d ng dysfunct on, not comp eted	0.00	# Unab e to ca cu ate a CI	0.997
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.00	# Unab e to ca cu ate a CI	0.991
Bladder injury	19.19	(1.47,251.25)	0.024
Surgery type			
F rst	Reference		
Repeat	3.53	(0.47,26.71)	0.223

Tab e *30*: Secondary popu at on: Co posuspens on: Return to theatre

Colposuspension	**Populations:** A pat ents		
Secondary outcome:			
Return to hosp ta w th n 30 days for procedure re ated event			
Yes vs No			
n=548			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			66
Characteristics	**Odds ratio**	**95% CI**	**p-value**
Age (decades)	1.43	(1.09,1.88)	0.011
BMI	1.00	(0.92,1.08)	0.968
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	1.07	(0.45,2.57)	0.875
Norma , vo d ng dysfunct on, not comp eted	0.00	# Unab e to ca cu ate a CI	0.987
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	0.88	(0.35,2.22)	0.784
Bladder injury	1.14	(0.20,6.63)	0.882
Surgery type			
F rst	Reference		
Repeat	1.53	(0.74,3.15)	0.247

Tab e *31*: Secondary popu at on: Co posuspens on: Return to hosp ta

Colposuspension	**Populations:** A pat ents		
Secondary outcome:			
Readm tted to hosp ta w th n 30 days for procedure re ated event			
Yes vs No			
n=726			
Multivariable analysis (accounting for Centre as a random effect)			
Number of mputat ons = 66			
Characteristics	**Odds ratio**	**95% CI**	**P-value**
Age (decades)	1.26	(0.96,1.66)	0.094
BMI	1.06	(0.98,1.15)	0.128
Pre operative urodynamic diagnosis			
USI, USI and vo d ng dysfunct on	Reference		
DOA, M xed, m xed and vo d ng dysfunct on	0.67	(0.22,2.01)	0.470
Norma , vo d ng dysfunct on, not comp eted	0.93	(0.11,7.63)	0.944
Grade of operator			
Consu tant	Reference		
Other (Assoc ate spec a st, subspec tra nee, spec a ty tra nee, other, staff grade, FTSTA)	1.04	(0.41,2.62)	0.933
Bladder injury	6.49	(1.95,21.55)	0.002
Surgery type			
F rst	Reference		
Repeat	0.81	(0.36,1.85)	0.623

Tab e *32*: Secondary popu at on: Co posuspens on: Readm tted to hosp ta

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Appendix 11: Errors returned from statistical programme

Outcome: Return to theatre for procedure-related event within 72 hours

Procedure	Population	Error
PUB	Primary population	No variability in the outcome, all No
AFS	Primary population	No variability in the outcome, all No

Outcome: Change in OAB - of those who did not have symptoms previously

Procedure	Population	Error
PUB	Secondary population (all patients)	Hessian is not negative semidefinite
AFS	Secondary population (all patients)	Not enough variability in the outcome
Colposuspension	Secondary population (all patients)	Hessian is not negative semidefinite

Outcome: Bladder injury

Procedure	Population	Error
PUB	Secondary population (all patients)	There were only 3 patients that had a bladder injury and so there is not enough variability in the outcome to fit this model

"Unable to calculate a CI"
There was not enough variability in the data to calculate the confidence interval for some of the data in the following.

Primary population – PUB	Change in OAB – in patients without pre-op OAB Readmitted to hospital within 30 days for procedure related event
Primary population - AFS	PGII Change of SUI Change in OAB – in patients with pre-op OAB Change in OAB - in patients without pre-op OAB Bladder injury Return to hospital within 30 days for procedure related event Readmitted to hospital within 30 days for procedure related event
Primary population – colposuspension	PGII Change of SUI Change in OAB - in patients with pre-op OAB Bladder injury Return to theatre for procedure-related event within 72 hours Return to hospital within 30 days for procedure related event Readmitted to hospital within 30 days for procedure related event

Secondary population (All patients) – PUB	Return to theatre for procedure-related event within 72 hours Readmitted to hospital within 30 days for procedure related event
Secondary population (All patients) - AFS	PGII Change of SUI Change in OAB - in patients with pre-op OAB Bladder injury Return to theatre for procedure-related event within 72 hours
Secondary population (All patients) – Colposuspension	Change of SUI Bladder injury Return to theatre for procedure-related event within 72 hours Return to hospital within 30 days for procedure related event

Appendix 12: statistical information on missing data and issues with analysis
Information provided by statisticians

Statistical plan for handling missing data: Provided by the statisticians at the start of the project

Within the 'all patient' dataset, predefined covariates that are missing (under the assumption missing at random) will be imputed using multiple imputation with chained equations. The number of imputations that will be conducted will be found when assessing the number of complete data for the predefined covariates for each patient. The percentage of complete data across these predefined covariates will then be taken from 100% to give the number of imputations to be used (1, 2). The multiple imputation model will include all the predefined covariates (to be imputed, or if complete auxiliary variables) including the outcomes of interest, treatment arms and centre of which these will be auxiliary variables. If the multiple imputation model fails due to conditional modelling, the covariates with conditional issues will be removed from the model.
For all analysis and outcomes the multiple imputed datasets will be used (3, 4). In the case where there is no multiple imputed data for a particular analysis then complete case will be used. This would occur if the multiple imputation model was unable to impute all the predefined covariates missing data as the optimal imputation model failed, for which the statistical model is fitting.

Post analysis report provided by statisticians

Multiple imputation has not performed optimally such that all the missing data requiring imputing a data value for, had not occurred, which is not uncommon. This was most likely because there was a large amount of variability in the data in the variables included in the model.
Additionally, variables that have conditional modelling issues with the outcomes meant that these variables were not imputed. Therefore, these variables will still have missing data values in the dataset. This was more likely to occur for binary and categorical variables rather than continuous variables.
Subsequently, it was found that the most optimal model given the data contained the pre-defined variables which did not have issues and the imputation method used was able to successfully impute the majority of data values.

This multiple imputation process was completed in the full dataset that contained all patients that underwent one of the 4 treatments. Under the primary analysis, the patients who had non-concomitant first surgery were included. As the multiple imputation was completed in the 'all patient' dataset across all treatments, and the data reduced down to subsets and per each treatment, there was no or not enough imputed data to calculate a 'between imputation variance'. This primarily occurs when the statistical model is being fitted to each of the 66 imputed dataset, and to combine these results it is required to take into account the 'between', 'within' and 'total' variance from the imputed dataset. If one of these variances are missing it means it is not possible to fit the statistical model using the imputed data.
If this was not possible 'complete case' analysis was performed where the original data was used and the statistical model was fitted to this. Missing data values for any

patient within the dataset given the covariates and outcome in the statistical model means they will not be included in the modelling. Therefore patients with ‘complete ’ data given the covariates and outcome specified in the statistical model will be included. This is still the case for when there is imputed data, those with missing covariate or outcome data will not be included in the analysis, but this is not called ‘complete case ’analysis as multiple imputation have been completed on this set of data i.e. the values are not strictly recorded straight from the data collection process.

Naturally the set of patients where imputed values have been used in the statistical analysis will have a larger number of patients included compared to complete case analysis (no imputed values). It seems to be evident that when we have in the ‘all patients’ population and ‘non-concomitant surgery’ patient population there were not enough imputed datasets that would fit the statistical model thus no between imputation variance was able to be calculated. However when we had a smaller set of patients, the ‘non-concomitant first surgery’ patients, this tended to include all 66 imputations when completing the statistical analysis. Therefore the imputed datasets were sufficient enough to complete the statistical analysis and hence included those patients where their missing data was imputed. This in turn means that we were able to include more patients in the statistical analysis.

“Number of imputations = 0: The combination of variables and outcome did not use imputed data, therefore results are based on non-imputed data (i.e. original data) Error code: No imputations to calculate the between imputation variance”

One thing to note about the primary analysis and some of the outcomes is that they do not all use the 66 imputations for the multivariable analysis. This is because in this population there were not imputed values to use, hence the original (non-imputed) data is used for these multivariable analysis (noted in the excel file).

Issues with the regression analysis

There are some data points that despite running the model the odds ratios could not be calculated. The model reported that convergence was not achieved or showed an error message or were unable to calculate the confidence interval. Some of the variables have been marked as omitted or no data, this is due to insufficient or no data that varies for that specific outcome of interest (this is mainly for the secondary outcomes) and for the AFS and colposuspension treatments.

“Convergence not achieved”

In accordance with the methods outlined in the statistical analysis plan, for these particular outcomes and set of covariates in this population for these treatments, it was not possible to statistically model this as there were convergence issues. Convergence issues usually occur when the algorithms for the analysis does not allow for a solution to be found, which can happen if there is not enough variation in the outcome, or the variables included into the model, or even the spread of data across categories. There is no alternative solution as the data is set. This can happen because not all people were able to be included as there may be missing covariate data. Multiple imputation is useful to minimise the amount of missing data there is, but it is fairly common, and seen in this analysis, that the multiple imputation was not perfect. Therefore there will have been a smaller number that were used in the

analysis. Again this would not reflect the variability in the outcome and also the variables in the dataset.

This has returned an OR and CI but it has not reached convergence. This has happened because the number of iterations of trying to fit the model has come to the default maximum and so it has tried to fit the model based on the last iteration and so the results are an approximation to what the model would have done if it had converged. This is a specific problem as it hasn't defaulted to its usual just stating it could not converge and doesn't give any results because it is too far gone. On balance it was decided to not report these findings when convergence was not achieved but there are results as it will not be the truest reflection on the data. The variability within the covariates or outcome or a combination of both will be the issue. This might be more likely to happen in the smaller subsets of patients and only looking at one treatment. There is likely to be very little variability in the data for these, it might be that in this population there are a very high proportion that were in the USI, etc group and very few in the other groups, hence the strange looking results.

"Error"

The tables in "appendix 11" lists and explains the errors seen. Some are due to limited variability in the data for which to fit this model and the other explanation from Stata is stated to be Hessian is not negative semidefinite. This means that the matrix within the model was not valid and therefore cannot produce the results for this model essentially meaning the model could not be fitted. The ones reported as "unable to calculate a CI" arise because there was not enough variability in the data to calculate the confidence interval.

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Appendix 13: Clinician questionnaires

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BSUG Questionnaire

Figure 1: BSUG members questionnaire

BSUG Audit Database use

The BSUG database now has over 90 000 procedures registered. The aim of this survey is to explore what the membership would expect to happen with the data. It is completely anonymous and your involvement is critical in making this a success. Clinical governance is the domain of your trust and not BSUG. We do however like the RCOG, have a role in setting standards, but not policing them and we acknowledge that many worry about the use of the database because of this.

The current governance arrangements are that applications for data from the database are made to the research committee, but the management of the database is through the database committee.

The following short questionnaire is only 8 questions and is aimed at informing the BSUG executive, research and database committees how the membership would best like the BSUG database to be used in generating reports. We would assure you, the members, that reports will always be anonymised. Individual reports will not be generated.

1. About you: Would you describe yourself in terms of the BSUG database (select one option)

- ○ Not registered do not use
- ○ Registered do not use
- ○ Registered very limited use
- ○ Registered regular use
- ○ Registered routine data entry NHS only
- ○ Registered routine data entry including private practice

2. Is your data entry? (select one option)

- ○ Just procedures
- ○ Procedures and follow up
- ○ Procedures follow up and chasing up as much missing data as possible
- ○ Not applicable

3. We are moving towards a time when more information about outcomes is being required and mandated. With this in mind, should BSUG use the database in some form to provide audit data? (select one option)

- ○ Strongly agree
- ○ Agree
- ○ Neither agree nor disagree
- ○ Disagree
- ○ Strongly disagree

4. One of the key points is that currently there are over 400 members registered to use the database, however the data entered is skewed and therefore potentially biased. The bias may be towards a few "high users" (e.g. top 20 users) or may be biased by the "low end" users who may have had selective data entry. Bearing in mind the pattern of data entry; if an audit is produced it should (select one option)

- ○ Include all data
- ○ Include data only from centres entering (a total of) over 50 cases total
- ○ Include data only from centres entering (a total of) over 50 cases a year for over 3 years
- ○ Units that have entered over 100 (total) cases
- ○ Other (please specify)

5. Bearing in mind your responses to the previous 2 questions, who should national data be available to for analysis for research or reporting outcomes? (via an approved request to the scientific committee) (select one option)

- ○ All BSUG members
- ○ Only BSUG members registered to use the database
- ○ Only members registered and who have entered data on the database
- ○ Only members who have entered over 50 cases
- ○ Only members who have entered over 50 cases for 3 years or more
- ○ Only members who have entered over 50 cases >50% follow up data
- ○ Other (please specify)

6. Referring to your answer to Q 5. Who should be involved in planning and writing up audits? (Tick all that apply)

☐ Any member
☐ ATSM trainees
☐ Subspecialty trainees
☐ Members registered to use BSUG database
☐ Members contributing >50 cases per year
☐ Members with follow up data
☐ Other (please specify)

7. Referring to your answers to Q5 & 6. If data is requested (which may incur costs of up to £1000) who should pay for the retrieval and analysis? (select one option)

○ BSUG

○ The individual requesting the data (including trust)

○ External party (e.g. commercial organization) on behalf of requesting clinician

○ External party

8. If you do not routinely enter data on the database what would encourage you to do so? Please enter free text into the box followed by any other comments

BSUG

If you do not routinely enter data on the database what would encourage you to do so? Please enter free text into the box followed by another other comments

 # Responses Date

Funding or Prices/grants for top 10 contributing units
I enter all data but slip up on follow up due to the haphazard nature of reviews (e.g. SHO / Reg may see patient). We must audit our data and have benchmarks by which to compare our performance - this is inevitable within all practice. Present barrier to entering data is that the database is only available at NHS facility. It seems one has to work very hard indeed to collect data.
Make it compulsory for anybody who wishes to do any prolapse or incontinence surgery
I need either time or help to be able to enter my data regularly and I am trying to get support
BSUG database app on mobile
Having greater clerical assistance
I am keen to register and enter data. So far transitioning between jobs, my theatre lists were infrequent, so I was waiting for a regular list. Now it is getting regular. So I will make an effort to register and enter data. Thanks
Making it easier and Mandatory
Make it compulsory in the UK
Copy the BSCCP and make data entry of a minimum of 50 cases per annum necessary to re- accredit as a BSUG member every 3 years.
I struggle to enter all the cases and this is mainly to do with the time- also no support for telephone follow up of defaulters!
Being more user friendly
Admin support i.e. Help and time
Ideally the PROM questionnaires should be electronic and patients should be able to complete them on-line and be linked to their BSUG database entry
if it was mandatory then we would all have to! consent seems a problem, and just getting the system up and running
Time!!!!
Participations in clinical trial, sharing experience with other colleagues and tertiary centres, comparing clinical outcomes
Data entry resource
Prohibited at present by lengthy process to obtain Caldicott approval to enter PII
I am a trainee so am not eligible to enter my own data yet.
I routinely enter data for my consultants, but as a trainee I do not yet enter data for myself.
make data entry mandatory
finding additional time in my job plan
The database needs a lot of work in its reporting capabilities. It should be possible for individual clinicians to look at reports of their own data on any variable that is input onto the database, and potentially comparing that to national figures.

the database should be available to all who do this type of surgery-free at the point of entry. BSUG is a charity, and this can be construed as a charitable duty.
very one performing the procedures should enter data. However, NHS hospitals should allocate time for individuals to do that as part of consultant Job plan
I do enter data but would feel more encouraged to do so if I was able to compare my results/ my unit results with those of peers
Initially difficulty with logging on, passwords etc.
I do enter data presently but facility to do so at home or access data has stopped. So many barriers within the service to collecting one's own data. Regrettably the only factor that works to encourage individuals to collect their own date is fear, be it litigation or revalidation.
I already enter the data. However, having safe encrypted system that would allow you to enter data from any computer would allow easier entry of private cases which then avoids transporting notes etc. to NHS premises before data can be entered.
The only thing that will encourage people to participate is to make it mandatory through trusts. People use lots of excuses for not using the database. My feeling is that much of this is a fear of publicly stating workload and results.
Support. The clinics and theatre lists are far too busy with admin to have any time to enter data. In my previous trust we gave patients the questionnaires and consent forms for the database, and these were given to the secretary who uploaded them as well as the operation data from the notes. She also sent out the follow up questionnaires and uploaded the data. This is then unbiased data compete data undertaken by someone who has time allocated to doing it.
There is an issue with regard to follow up, if the DOH wants valid outcome measures, they need to sign up for appropriate follow up of patients in order for the data to be robust.
If it were less time consuming
Gynaecologists should only use BSUG database if all consecutive cases are included. This should be a mandatory requirement before registration and checked at accreditation or spot audits
database is very time consuming and not all, consultants have time to enter it. also follow up data is difficult to enter as patients may be seen by team members who do not input data
It cannot be used as an effective audit tool unless data entry is mandatory and entered by support staff rather than clinicians
I think when the surgeons collect the data there is always at least an involuntary bias, this can be some selection of patients, selection of complications, etc. For the data to be used reliably to set up standards and audit people's practice, I believe a third party should collect them. Surgeons could introduce surgical data, but a third party should phone the patients and check for complications and patients reported outcomes.

Table 1: Responses for BSUG not routinely entering data

Themes and codes

BSUG

- Logistical barriers
    - Initial set up
        - Caldicot
    - On going
        - Time
            - Theatre
            - Clinic
            - Chasing DNAs
        - Personnel
            - Admin
            - Juniors
        - Consent
        - Ease of access
            - Private/home/mobile phone
        - Funding
- Data bias
    - Requirement for compulsory entry
    - Outcome data collection separate to clinical team.
- Fear
    - Of publicly stating results
    - Of revealing work loads

- Prospects for future development
    - Sharing experiences
    - Learning from others
    - Developing trials

IUGA Questionnaire

IUGA Questionnaire

1. In what country do you practice?

2. Do you have a national urogynaecology database in your country?

3. Is the database mandatory? 4. Who mandates it?

5. Is it fit for purpose? 6. Why or why not?

7. Do you see the need for an international database provided by IUGA? Why or why not?

Figure 2: IUGA members questionnaire

Results Questions 1

Country	Total	Country	Total	Country	Total
Argentina	4	Ireland	4	Russia	3
Australia	17	Israel	6	Saudi Arabia	1
Austria	3	Italy	4	Serbia	1
Belgium	2	Japan	2	Singapore	1
Bolivia	1	Kenya	1	Slovakia	1
Brazil	11	Kuwait	2	Slovenia	2
Canada	9	Latvia	1	South Africa	7
Chile	12	Lebanon	2	South Korea	1
China	2	Malaysia	11	Spain	11
Columbia	1	Mexico	8	Sudan	1
Czech Republic	2	Mongolia	1	Sweden	2
Denmark	5	Mozambique	1	Switzerland	7
Egypt	1	Namibia	1	Taiwan	1
Ethiopia	6	Nepal	2	Tanzania	1
Finland	1	Netherlands	12	Thailand	4
France	1	New Zealand	6	Turkey	2
Germany	7	Nigeria	3	Uganda	4
Ghana	1	Pakistan	5	UK	40
Greece	1	Peru	4	United States	21
Guatemala	1	Philippines	3	Uruguay	4
Hungary	1	Poland	5	Venezuela	1
India	14	Portugal	3	Zimbabwe	1
Indonesia	1	Romania	1		

Table 2: Respondents for IUGA questionnaire by country of work

Question 5 + 6: Is the database in your country fit for purpose? Why or why not? Additional information

See main text for further information - UK answers supplementary – BSUG database

Yes	Covers all but BSUG owned
	It would better if it was mandatory and compliance checks were made
	In depth, difficult access however it is for data protection
	Comprehensive, includes follow up, validated
	Provides data fir appraisal
	Long standing and well recognised
	Able to give statistics for appraisal, helps in outcomes
	It includes all information required
	Covers all urogynaecology procedures
	Covers all parameters
	It is
	Mostly functional for audit and simple research queries
	Designed by a great team
	All data collected
	Captures relevant data
	Database maintained
	National BSUG Database - been running for almost 20 years. Provides a lot of very good national reports as well as being useful in research and consultant appraisal
	But should be compulsory
	Addresses all areas and still been improved
No	Not legally mandatory. Not formally logging prostheses. Required clinicians to input which = burdensome.
	No option to say don't know - I've not seen or used the IUGA database - I use BSUG
	Need to be mandatory to get a clear picture
	As it is not mandatory, the surgeon can choose which patients are included. Unless every consecutive case in included, it defeats the purpose. Secondly the follow up can be done by the surgeon who operated on the patient and therefore subject to bias.

Table 3: Respondents for IUGA questionnaire: is your national database Fit for purpose: UK answers supplementary – BSUG database

Yes. It would be useful for physicians
I don't see a need for international database as practice varies between countries. My main concern is validity and accuracy of data. There will always be reporting bias as the performing clinician will be entering data. Bad outcomes or complications may not always be entered. The negative incentives currently outweigh the positives. Implications of patients accessing this data when only selective entry is made by clinicians. All clinicians - i.e. generalists and urogynaecologists should use the database if advocated for non-mesh procedures. A national data base that is mandatory is helpful as this qualifies for admin time and allows audit process to check for accuracy. An international society like IUGA can guide other societies with its experience and technical support. IUGA has advocated for databases and should continue to do so. Currently there is no patient consent for using the database. I am still using the database but struggle with time for data entry.
no, but a database committee would be good to compare the different databases and feedback to countries
While there are no national databases, there is a society based database (UGSA), a fledging pelvic mesh database and a couple of gynaecological databases. So it would be unlikely to be used by Australian clinicians
you would have to contact UGSA
Yes, to have ab access to international database
Yes. More authority, better picture of international practice
yes, information and learning should be global
I already use a data base - Surgical Performance - this is international
yes - it would be helpful for comparing stats and standardization
Yes, fir countries that may not have one.
No. I see the need for a universal tool or categorizing system but there are so many jurisdictions with differing regulation that it would be difficult to have a one size fits all
No need for international database as results are uninterpretable.
It would be preferable to have one on a national level that could contribute to an international database. Nevertheless, since most national associations are failing to provide a database it might be necessary for IUGA to step in and provide one. Unfortunately not all pelvic floor surgeons are IUGA members which will be a limitation.
No. Too big. Maybe a kind of template that every country can use.
No, difficulty with privacy regulations
Yes! To build evidence-based practices
Yes! It will be very important as a data bank
Yes. It would be helpful to medical research and guidelines.
Yes! To know about the surgeries people are performing and results, complications
yes, but difficult to implement due to time constraints, and need to double enter data (in patient chart and in database) - need for national database that does not require double entry - and somehow that data could then be merged internationally if possible (although unlikely)
No. Should be by country

Yes, it would be informative.
This would be very biased because of what people opt to put in. Thus, I don't see it as very useful
More information is always better
Yes, but complex due to current multiple registries (EMR, current research DB), so a new one will imply probably a third registry for the same patient. This makes it not very feasible
Yes - because it's important for professional certification
Yes, because is very important to know other experience and practice in urogynecology
yes, to improve in all aspects
Yes. Because of whole world information, great number of cases, big data.
Yes, objective comparison option
No, we have a national database.
I think it will be difficult to implement.
Yes. Denmark is a small country with no big data. An international database would host big data and help robust research and clinical awareness.
No, we will in time have a mandatory registry and database in the UK and I personally would not use an international database on top of this
Yes, it helps to standardize the care and generate a worldwide data.
Yes, I see the need. Significant numbers of obstetric fistula and severe stages of UVP. Not much essential data for clinical practice available. No national directory for practitioners. The discipline itself is not well known and understood.
Yes, we need evidence-based practice
Yes, to have a better overview about success and complications
Yes. Gives easy access to global surgical burden and trends. May provide direction for training and sharing of expertise
Yes. This would bring it globally
I want such data base; it will be helpful for future evidence base practice
It's the need of the hour
Yes. It is an emerging specialty and patients are not getting guideline-based treatments at present.
Yes. It will provide a uniform format of record keeping and collection of national data for accredited urogynaecology surgeons in any country
Yes. It would be useful to have international database so we can learn from each other
Yes, because we can use the data for our project research
Yes. To include those without a national database and to provide standardised comparisons between countries
Absolutely Otherwise it will not happen
Yes Research
Yes, for regulations and guidelines
Yes. To have an accurate database on the outcomes of our surgical treatment
We have a very exhaustive database in according to IUGA

there are terrific discrepancies among different countries after the FDA warning, so I don't know
Yes. I like to share my experience with other colleagues
oh yes! Will help with the growth of Urogynecology as a subspecialty in Kenya
Yes - to assess and log
Yes, I use it in my clinical practice
Yes, in order to understand the variation of managements
Yes - many cases
Yes, database is very important in daily practice
yes. Helps to strengthen evidence-based practice all over the world
Yes, to help identify breath of urogynaecological diagnosis, types of management and to standardize treatment across the world to improve the outcomes for these patients
Yes, to look for outcome and trends of surgeries with better number of cases available
Yes. Enable access to prevalence of certain condition
Yes, to learn from each other. We can compare the surgical outcome; however I am not sure how many people are willing to share their patients' outcome....and transparency on how this data shall be utilised, and the ownership of the data need to be clarified.
To have a standardised database
Yes, it's important to have access to information about surgery results and complications.
Yes. It is important to have information of outcomes and practices to guise our practices
Of course it’s the only way to keep good track of long term follow up
Yes, to have contacts on all country
Yes, just to know how Urogynecology is running in the country
Urogyn is new part of Mongolian medical system
Yes, as we have huge prevalence of PFD, this will give idea for research
Yes. To keep record and audit
Yes, to maintain the database for our reference and cross references
maybe. we do have a database for mesh procedures. a database for all urogyn procedures could provide insight in complications or recurrent prolapse
Would be good, but best if it is connected to the local system and not and extra system
Yes, to see, understand and predict numbers of prevalence and operation numbers.
no, regulations will prohibit that
would be nice but linking it with current electronic patient files will not be easy, and entering data twice is not an option. What about privacy?
Yes - what to do – indication, complications, recurrence
Yes. To evaluate the outcome of treatment on the long term.

maybe, international collaboration could reduce the costs of a database. But not if we have to register nationally as well. The Netherlands only has a urogynae surgical database
Yes. A standardised database would be less expensive and uniform for all countries.
Yes. Database will help in the assessment of performance and identification of deficiency areas so that tailored expert interventions could be offered or suggested. UG is gaining popularity worldwide due to ageing populations and increasing awareness among women with great emphasis on quality of life. International database provided by IUGA will be of great benefit.
Yes. It important for evaluation and monitoring. Also, it helps with assessing areas of focus in terms of training
helpful in maintaining records and help in improving complication rates
Yes, there is a need
Yes, it would be very good to have a follow-up of the patients
Yes, I do. Because we need to organize the results of managing our patients and communicate and the possibilities to work in a multidisciplinary way
Yes, because it will allow to know who are doing the things well and what they are doing.
Yes. For statistics & knowledge
Yes. To Monitor epidemiology, surgery efficacy dependent on canters volume, to facilitate multicenter studies
Yes, it would help to centralize outcomes and establish common management pathways.
yes/ collaboration
Yes, because big data is very important for analysis of our surgical results.
Yes, urogynecology needs to be overviewed and observed
Yes, to share experience and develop research
Because of purposeful
Depends on what kind of database we're talking about.
Yes, it would be helpful and a great source of data for research
Yes, for auditing of services and early detection of issues related to complications
Yes, because it could be a way to obtain statistics of our surgeries instead there´s differences in the treatments
Yes. It’s the only way to compare your results
Yes. It would be easier to work and to perform "big studies"
Yes, it is important in themes of research
Yes, especially in countries where there is no national database, as Spain. I think it could be a great help national research projects, as well as improve the quality of data collection, unifying criteria.
Yes. I think an international database will facilitate the data collection in a homogeneous way, as well as according to the guidelines recommendations. It will help to the collaboration between different countries, as well as to compare results. In addition, it will be very helpful for countries without national database as Spain.
TO DEVELOP ALL THE PROFESIONS AROUND PELVIC FLOOR

Yes, because it's the way to collect information about surgical procedures and its results
Yes. It can be of great help for countries where this type of database does not exist. It can also facilitate multinational research projects, ensuring quality data collection, with validated instruments and a subsequent analysis of the results with the appropriate outcomes.
Yes, I do. It's necessary for to know the complications, results…
Yes, there is a need for it, as it helps a lot in treating and helping patients of urogynaecological conditions around the globe.
Would be interesting but I cannot say it is absolutely needed.
good idea. with a mandatory brief data compilation (age, surgery, mesh, follow-up) and an expandable, individual data set (questionnaires, urodynamic parameters etc.)
Yes. This would allow surgeons and patients to have a better understanding of objective and subjective results, as well as peri-operative complications
It would be a good idea. a short one with some mandatory data would be good. Expandable on an individual basis
Not sure - extra work. Garbage in garbage out
Yes. Because we did not have in our country. Almost urogynecologist are the members of IUGA. It is good for us to attend the international database.
Yes, I see the need. It's important for motoring the Epidemiology of Urogynaecological conditions.
Yes, for national data
Yes, to have big data.
I think that it has an extra value to have an international database. For comparison of methods, outcome, effectiveness, etc.
Yes, we need large population size to make clear decisions and long-term consequences
Yes, it would be useful for research and collaborative work
yes, this is the only way to document the burden of disease, treatment options, and follow-up for patients
Not yet. We need to see how to first get one established in the country.
I think it's of great value Because data can be used to identify burden, trends and needs at a global picture
Not in the UK as the IUGA DB mimics the BSUG one mostly. This is even more complicated now as the NHS is introducing a national mesh registry too- hopefully this will sink with BSUG
No, UK developing one that is UK legally compliant
No. National database is sufficient
Not at this time to avoid duplication
Yes, will provide comparable outcomes across the world
Yes, for countries without a database
Not personally but I can see the need internationally. Ideally some core data from national databases could be synched with the International one but I recognise that could be challenging technically and legally
No, already have one

As already doing in the UK, it will be a repeat work, so no international database needed. BSUG could allow the data for sharing with the IUGA for comparative data
No as we have national database
Each country should see to their database
No, as we are having a national mandatory DB and so don't want to duplicate
National one is adequate
Makes sense but only if mandatory in each country.
BSUG is pretty good
Good idea for countries without a mandatory database
Yes, but suggest you give members a reason to use it. For example, follow the lead of the BSUG Database and produce Reports from the database and Summaries which users can download for their Appraisal
No. Current UK one is fine
No as we already have one. Another issue is migrating data from one database to another.
Perhaps not - since approach is different in different regions
Yes, help to improve care and gain better understanding
This would be a great asset for those who are unable to record and audit their data using a national database. Audit and recording of procedures is likely to become mandatory in many countries and protects clinician and patients
Yes, but if all consecutive cases are not included then it defeats the purpose of a database particularly if we wish to know about complications. We should also use validated outcomes and have long term follow up.
yes, as not all countries have one. The IUGA database is a shortened version of the UK's (BSUG) database.
No - use BSUG Need decision to use one or the other
No - difficult to manage and consent issues of different countries
No - The input of data is time consuming. I would support and international collaboration and sharing of national data
Great for those without a local database to use
No - too complicated trying to do a national one with AUGS
No. Procedure approval varies from country to country. Until uniform each country or region should manage its own
Yes. To compare results, epidemiologic data, etc.
No as practice patterns are quite different. Not sure how much additional value would be added
Yes, would help with research and quality improvement
No, we have one from AUGS.
I believe individual countries should have a database to serve their needs and then have international collaboration on refinement and metrics.
If we can use it for research purposes
An international database would be a huge benefit to the urogynecology community
No. Too expensive. It should be government sponsored.

Yes, patient education
In my country there are no reliable records of course they are necessary
Yes, allows to understand depth of problems in different communities. Comparisons in Research
Yes, to improve our knowledge and do better for our women

Table 4: Respondents for IUGA questionnaire: Do you see the need for international database provided by IUGA? Why or why not?

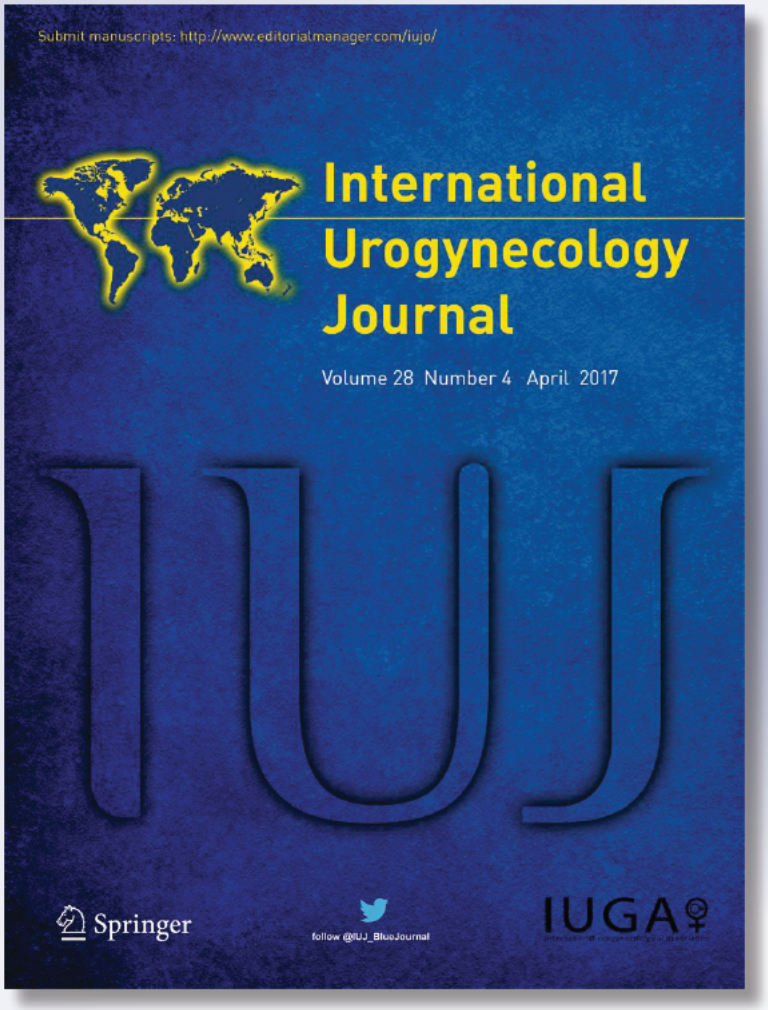
What can we learn from large data sets? An analysis of 19,000 retropubic tapes

Fiona Bach & Philip Toozs-Hobson

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ORIGINAL ARTICLE

What can we learn from large data sets? An analysis of 19,000 retropubic tapes

Fiona Bach [1] · **Philip Toozs-Hobson** [1]

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Abstract
Introduction and hypothesis Retropubic tapes are successful for treating stress urinary incontinence (SUI), but there is controversy around risk profiles. The British Society of Urogynaecology (BSUG) database allows analysis of surgery for patient safety, surveillance and benchmarking. Objectives of this study were to establish success and complication rates in routine practice, determine complication rates for trainees and consultants, explore reasons for outliers and assess perforation as a surrogacy of quality.
Methods Approval was obtained from BSUG to use data on retropubic tapes. Data was anonymised, and patients gave prior consent. Analysis was done using the χ^2 test, and a funnel plot of bladder perforation rate was calculated.
Results There were 18,763 procedures recorded: 14,156 were performed by consultants, 64 by associate specialists (64), 1140 by subspecialty trainees, 2549 by registrars, 201 staff grades and 377 other. We found a 3.5 % bladder perforation rate, which was statistically higher for trainees than consultants ($p < 0.05$). The rate of other "standard" complications were low: 95.8 % of patients felt better on the Patient Global Impression of Improvement of Incontinence (PGI) scale. There was a significant difference ($p < 0.05$) in PGI and SUI outcome between patients who did and did not experience perforation.
Conclusions Success rates with retropubic tapes are high, with low complication rates. Bladder perforation in "real", not "trial" data was 3.5 %, which is lower than reported by the Cochrane review (4.5 %). Trainees have a higher perforation rate ($p < 0.05$) because of learning curves. Outliers are easily identified, and reasons for this should be explored, including proportion of trainees doing the surgery. This analysis confirms that bladder perforation is a valid surrogate for quality with a small but measurable difference. We have a responsibility to analyse data to improve patient care and encourage colleagues to support the International Urogynaecology Association (IUGA) database initiative.

Keywords Retropubic tape · Outcome measures · BSUG database

Abbreviations

SUI	Stress urinary incontinence
NICE	National Institute for Health and Care Excellence
BSUG	British Society of Urogynaecology
MUS-TVT	Midurethral sling–tension-free vaginal tape
SST	Subspecialty trainees
ST	Specialty trainees
FTSTA	Fixed-term specialty training appointments
UDS	Urodynamic studies
PGI	Patient Global Impression of Improvement of Incontinence

Introduction

Retropubic tapes have been used for 20 years for treating women with stress urinary incontinence (SUI) [1]. Their success has led to them replacing colposuspension as the gold standard procedure for SUI. In view of the current controversies relating to the use of mesh and tape procedures, several bodies [2–4], including

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the National Institute for Health and Care Excellence (NICE) in the UK, have issued recommendations that all urogynaecology procedures should be entered onto a database such as the British Society of Urogynaecology (BSUG) database to ensure robust follow-up. As a result of these concerns, the International Urogynaecology Association (IUGA) are developing their own database along similar lines to the original BSUG database.

The BSUG database [5, 6] is widely used in the UK as a tool by which urogynaecological procedures are recorded. Patient characteristics, outcomes and complications are entered immediately postoperatively and at follow-up appointments. Since the launch of the Internet based version in 2007, it has become increasingly popular, and at the time of this writing, slightly more than 93,400 urogynaecological procedures had been registered. These data can be used on an individual level to benchmark personal practice or in a much wider setting to explore trends, complications and success rates across the UK, thus giving it a major role in patient safety [7]. The database allows clinicians to evaluate their own practice and compare it with national findings and counsel their patients accordingly using personal statistics. It is our view that individual clinicians have an ethical responsibility to use these data to improve patient care. We show how data can be analysed and warn against pitfalls of crude analyses. A key founding principle is that data must be used appropriately. BSUG has no statutory mandate for regulation, and it is enshrined within BSUG that there will be no overt or covert internal or external body of review.

Our objectives for this study were to establish success and complication rates in routine (non-trial) conditions and complication rates for trainees and consultants and to explore the reasons for outliers and the possibility that perforation may be a surrogate of quality.

Materials and methods

Separate ethical approval was not required. Each individual centre went through the Caldicott Guardian process, and each patient gave written consent to the use of their anonymised data prior to being entered on the database. The database is overseen by a committee, but applications for analysis are reviewed by a separate research committee, giving two levels of review prior to data release. Permission was given by the BSUG research committee to analyse data on midurethral sling–tension-free vaginal tape (MUS-TVT) (Ethicon Gynaecare, NJ, USA), Advantage and Advantage Fit (Boston Scientific, Boston, MA, USA) tapes from the start of the database in 2007 until 27 January 2016, and this analysis was undertaken under the auspices of the database committee to aid the development of the first national audit. Data were anonymised at the source so that individual patients, doctors and units cannot be identified. Bladder perforation and other complications were assessed. Data were analysed using Excel and chi-square test. A funnel plot was generated using standard methodology [8]. Patient Global Impression of Improvement for Incontinence (PGI) was recorded in the standard fashion [9] of a seven-point scale of very much better, much better, a little better, no change, a little worse, much worse or very much worse. These were then grouped to better, no change and worse for analysis. Change in SUI (i.e. leaking with activity) was recorded under the following headings: cured, improved, no change, worse or never present. Follow-up varied between 6 weeks and 12 months based on individual unit practice. Patients were followed up in outpatient clinics or by postal questionnaire, telephone appointment online, at their general practitioner's (GP's) office or other individual preference.

Results

During the time frame, 18,763 primary tape procedures using the devices mentioned were entered into the database from 124 centres. The number of tapes entered per centre ranged from 1 to 1721. The 14,334 (76.4 %) were performed by consultants, 64 (0.3 %) by associate specialists, 1147 (6.1 %) by subspecialty trainees (SST), 2556 (13.6 %) by specialty trainees (ST), 202 (1.1 %) by staff grades, 7 (0.0 %) by fixed-term specialty training appointments (FTSTA), 189 (1 %) by others and 264 (1.4 %) had no grade entered.

Bladder perforation

We found 18,494 (99 %) records contained data as to whether a bladder perforation had occurred or not: 269 were eliminated as data missing from calculations. Overall perforation rate was 3.5 %. The funnel plot (Fig. 1) shows bladder perforation rate per centre against cases entered per centre. The overall perforation rate of 3.5 % is marked on the figure with upper and lower control limits, as shown. The limits represent ± 3 standard error (SE).

Bladder perforation per grade

Perforation rates of each surgeon grade were calculated (Fig. 2). The grade with the highest perforation rate was specialty trainees (8.9 %), followed by staff grades (8.0 %). Subspecialty trainees had a rate of 5.4 %, with consultants and associate specialists having the lowest rates of 2.2 % and 1.6 %, respectively. Trainee (SST + ST) bladder perforation rate was significantly higher than consultants ($p < 0.05$) (Table 1).

Outliers

Outliers were identified and breakdown of surgeon grade performing the procedures studied and compared to the entire

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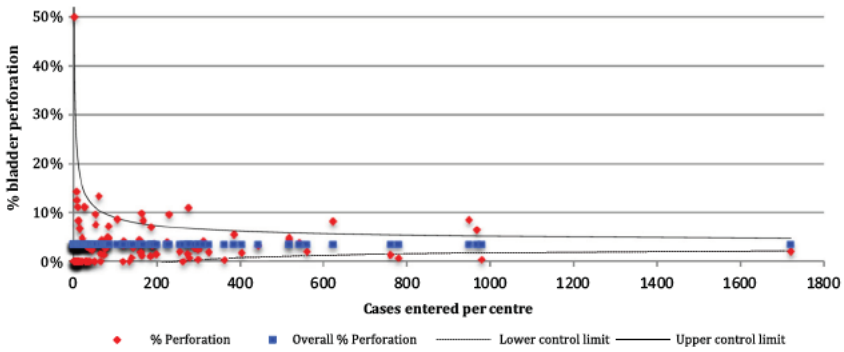


Fig. 1 Percent bladder perforation vs cases entered per centre

database. When looking at the entire data set, 4338 (23.5 %) cases were performed by non-consultant-grade surgeons (Fig. 3), and these accounted for 326 (51 %) of perforations. In centres where a higher proportion of procedures were performed by consultants, there was a lower overall perforation rate. This is demonstrated by the following examples: Centre A with a low perforation rate of 1.3 % had only 4.5 % non-consultant-grade surgeons (Fig. 4) compared with 45.3 % non-consultant-grade surgeons at Centre B, which had a high perforation rate of 8.5 % (Fig. 5).

In the three "high outliers" (Fig. 1), consultant bladder perforation rates were 6.0 %, 2.9 % and 4.5 %, and trainee rates (SST + ST) were 11.8 %, 15.8 % and 11 %. The centre with the most significant outlier was aware and had undertaken an audit to validate data; one clinician voluntarily arranged to have their practice reviewed and visited another centre to do a "refresher" in technique training.

Other complications

The BSUG database has a "Standard" complication set, and complications rates within 30 days are reported. These complications include blood loss >500 ml, vaginal buttonholing, graft complication, perioperative blood transfusion, bladder injury, urethral injury, vascular injury, bowel injury, neurological injury, ureteric injury and death. Results are tabulated on the database for surgeons to complete (Table 2). The frequency of these complications was gratifyingly low across the board, and as such, even with such a large data set, we were unable to identify trends or significances.

The same absolute number gives a different complication rate, as there were incomplete data either due to incomplete entry by clinicians; also some fields only featured in later versions of the database after modifications.

Patient Global Impression of Improvement of Incontinence

There were 11,366 (61 %) records containing outcome data including the PGI. This figure will always be slightly lower than the true result, as the database is live, so a delay of up to 12 months will occur after entry on the database while the patient goes through follow-up. We would estimate this currently to be in the region of 600 procedures, or ~3 %. Of the 11,366 patients, 73.5 % reported their PGI as very much better, 17.4 % as much better, 4.9 % as a little better, 2.5 % no change and 1.7 % reported a deterioration as being either little/much/very much worse (Table 3). This shows retropubic tapes continue to achieve good short-term outcomes.

There is variation as to how and when this data was collected; i.e. the follow-up regime: 33.8 % of patients were reviewed after 6 weeks, 34.5 % after 3 months, 28.1 % after 6 months and 3.6 % after 12 months; 79 % returned to an outpatients clinic, 11 % completed a postal questionnaire, 8.7 % used a telephone appointment, with the remainder (1.3 %) being followed up either online, at the GP's surgery or according to other local arrangements.

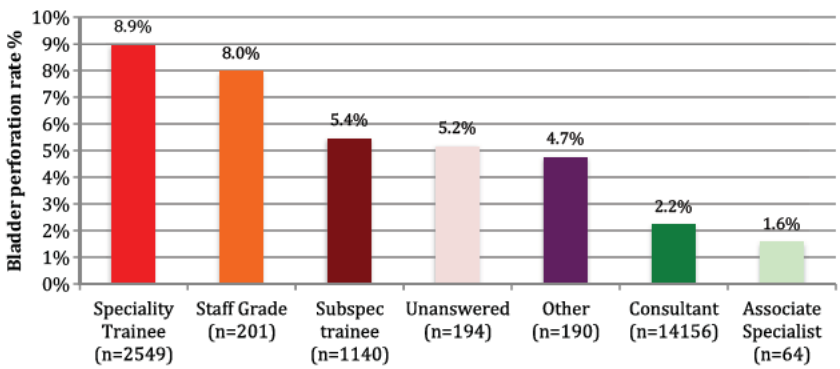


Fig. 2 Bladder perforation rate for each surgeon grade

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Table 1 Chi square test to compare bladder perforation rates between consultants and trainees

	Consultant	Trainee (SST + ST)	Marginal row totals
Perforation	313	290	603
No perforation	13,843	3399	17242
Marginal column totals	14,156	3689	17,845 (grand total)

Chi square statistic = 286.1397; p value = <0.05

SST subspecialty trainees, *ST* specialty trainees

Bladder perforation vs PGI and SUI symptoms

There were 11,204 (60 %) records that contained complete data sets to evaluate the link between bladder perforation and PGI. When comparing PGI, 95.9 % of patients felt better, with no perforation, compared with the 93.4 % who experienced perforation (p 0.02) (Table 4).

We then analysed SUI only: 11,401 (61 %) records contained complete information for evaluation; 96.7 % patients felt their SUI was cured/improved compared with 93.9 % who experienced bladder perforation (P 0.006) (Tables 5, 6 and 7).

Grade of operator vs PGI and SUI symptoms

In view of the significant differences between consultants and trainees with regards to bladder perforation rates and the significant differences in PGI and SUI symptoms following such perforation, the obvious progression would be to assess the difference between PGI and SUI symptoms and surgeon grade. We found no significant difference with regards to PGI or SUI symptoms when comparing trainees to consultants.

Discussion

This analysis represents the largest assessment to date and is a real-life data set. It further confirms the short-term surgical safety of these types of retropubic tapes: 95.8 % of patients felt better, and only 1.7 % of patients reported being worse. This analysis did not specifically look at urodynamic diagnosis: that topic will be further explored in a future analysis.

The overall bladder perforation rate in this self-reported cohort was 3.5 %. This represents "real" rather than trial data. This value is lower than the value of 4.5 % from the most recent Cochrane review [1]. One explanation for this may be that the clinicians who use the database are a self-selected group of doctors who are confident to have their figures audited. Another reason may be that the data entered is not correct, either by design or accident. Alternatively, it could be that some papers in the Cochrane review included surgeons still going through their learning curve.

It is expected that there will be a range of perforation rates seen at difference centres depending on a number of features involved; therefore, the upper limit shown on the funnel plot in this study could represent a "safe range" for an appropriate level of perforations. The outliers can be clearly identified on the funnel plot. However, lying above the upper line does not necessarily mean there is a major problem, but the reason for this variation should be explored. As mentioned, this situation led to a self-directed examination of practice in one unit. There are a number of reasons why perforation rates may vary, including operator skill, still being on the learning curve, a difference in case-mix complexity and incomplete data entry.

There are many centres that have entered only a small number of cases, meaning a small absolute number of

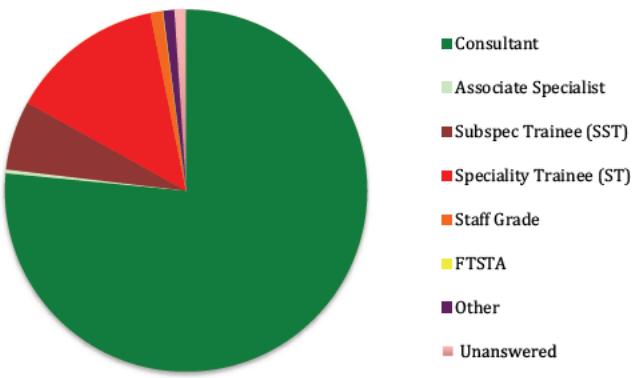


Fig. 3 Surgeon grade for the entire British Society of Urogynaecology (BSUG) database: perforation rate 3.5 %

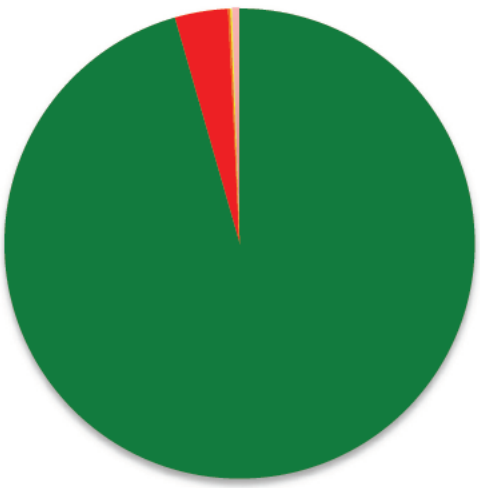


Fig. 4 Surgeon grade: low perforation rate of 1.3 %

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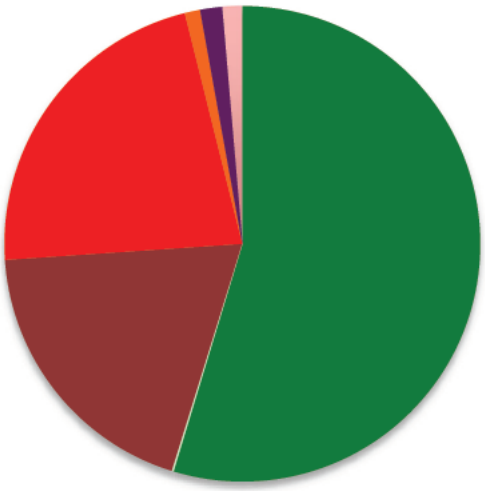


Fig. 5 Surgeon grade: high perforation rate of 8.5 %

perforations gives a greater impact on their rate. This is evident on the funnel plot, with one unit having a 50 % perforation rate but only two cases entered. We considered removing these centres from the analysis, but when combined with all other centres in the funnel plot, data can be interpreted. This range of complication rates does suggest that a wide range of surgeons enters cases into the database and not just the very experienced surgeons. It also adds weight to the inference that data entry is complete. There will also be new people adding data, and more experienced consultants may retire, so the experience will remain dynamic. Additional reasons for a higher perforation rate seen with lower numbers of cases entered could be because doing a lower number of cases may mean they are less practiced and therefore actually do have a higher perforation rate. It could represent an isolated run of complications or "clustering", which can happen with any event, and shows how important it is for all cases to be entered. Single-point measurement is possibly limited other than in extreme cases, and observing individual trends where the perforation rate settles down over a longer period may be important. Likewise, sectional analysis by annual perforation rate may give greater granularity of the trend, which is something individual surgeons can do easily in their own analysis.

Table 2 Percentage rates of "standard" complications

	Percent	Overall number
Blood loss > 500 ml	0.6	108
Vaginal buttonholing	0 5	57
Graft complication	0 5	32
Perioperative blood transfusion	0.1	19
Urethral injury	0.1	14
Vascular injury	0.1	11
Bowel injury	0.0	4
Neurological injury	0.0	2
Ureteric injury	0.0	1
Death	0.0	1

Table 3 Patient Global Impression of Improvement of Incontinence

Variable	Percentage
Very much better	73.5
Much better	17.4
A little better	4.9
No change	2.5
A little worse	0.7
Much worse	0.7
Very much worse	0.3

The appearance of the funnel plot was not as expected: instead of tending towards the overall perforation rate as the total numbers in each centre increased, the opposite has been shown; also, all centres with the greatest numbers of cases, >350, are outliers. Lying under the lower limit shows an impressive low level of complications. The outlying centres, with large numbers, were analysed in greater detail. Centres with high perforation rates had a greater proportion of procedures performed by trainees (see Figs. 3, 4 and 5); conversely, centres with low perforation rates had a greater proportion performed by consultants.

In the three "high outliers" (Fig. 1), consultant bladder perforation rates were 6.0 %, 2.9 % and 4.5 %, and trainee (SST + ST) rates were 11.8 %, 15.8 % and 11 %. With this variety in surgeon grade and rate per grade, the recommendation is that perforation rates be broken down by grade. As discussed above, one centre has already used this method to review practice and thus improve outcomes.

A significantly greater perforation rate is seen in trainees (SST + ST) compared with consultants, which explains the higher perforation rate in centres with a large proportion of cases performed by trainees. Trainees are a heterogeneous group, and many will still be on their learning curve when data is collected [10, 11]. Although we had data to establish how many procedures were performed by trainees at each centre, necessarily, we were without specific details, and it was not possible to know details of individual trainees at each centre. As such, it was not possible to establish where they were on their learning curve, which may be confounded where individual consultants may

Table 4 Chi square test to compare the implication of bladder perforation on Patient Global Impression of Improvement of Incontinence (PGI)

	No perforation	Perforation	Marginal row totals
Improved	10425	311	10736
Not improved	446	22	468
Marginal column totals	10871	333	11,204 (grand total)

Chi square statistic = 5.0611; p value = 0.0244

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Table 5 Chi square test to compare the implication of bladder perforation on Improvement of stress urinary incontinence (SUI)

	No perforation	Perforation	Marginal row totals
Better	9760	292	10052
Not better	330	19	349
Marginal column totals	10,090	311	10,401 grand total

Chi square statistic = 7.4973; p value = 0.006

Table 7 Chi square to compare the difference in stress urinary incontinence (SUI) improvement between trainees [specialty (ST) and subspecialty (SST)] and consultants

	Consultant	Trainee	Marginal row totals
Better	7908	1885	9793
Not better	266	68	334
Marginal column totals	8174	1953	10,127 (grand total)

Chi square statistic = 0.256; p value = 0.612854 (not significant)

alter the technique of the trainee, potentially moving them back on that curve. A single trainee who is already competent is likely to have a lower perforation rate than a group of trainees all early in their learning curve. As it is not practical to prevent trainees operating, to avoid the higher perforation rate, the best ethical option is to limit the number of trainees on the learning curve by only permitting trainees with a specific demonstrable interest in urogynaecology to perform tapes, thus limiting the numbers at the start of the learning curve at the same time. Training centres should consider designing training models to be used prior to operating on humans so they are not just beginning their learning curve when they start operating on patients [12]. Currently, the database does not allow trainees to register their personal cases, but changing the system could allow trainees to use it as their log book and track their progression, which perhaps is a key recommendation for the developing IUGA database. Overall, we would argue that despite a higher trainee perforation rate, these results are strongly encouraging. The lower perforation rate found in this study than those published in the literature suggest that our teaching and performance regarding TVT insertion is improving with time.

Reassuringly, other standard complication rates were low (Table 2), and no trends were identified. Although it is interesting to calculate bladder perforation rate, if there is no impact on outcome for the patient, then it is merely a marker of a complication rather than outcome and is less important. Since there was a statistical difference (p value 0.02) in PGI between patients who experienced perforations compared with those without means it is a valid surrogate for quality. Hence, we support and confirm that this is an important measure. A significant difference (p value 0.006) in improvement of SUI between perforations and no perforations further supports this. This effect, however, is likely to be an underestimate, as difficult cases are more likely to be performed by a senior surgeon and therefore there are relatively more perforations in the "easier and less complex" group. It can be concluded that there is an association between bladder perforation and a poorer outcome, but the perforation may not be the cause of a worse outcome. Possible explanations include a surgeon who is less skilled is more likely to perforate; the impact on the patient being told of a complication and therefore thinking the operation was less successful; or that when the tape is repositioned following a perforation, the TVT is placed differently in order to avoid a second perforation, which may lead to a less beneficial outcome. We were unable to demonstrate a link between outcome and surgeon grade, suggesting that it is the presence of the perforation that leads to the poor outcome.

Table 6 Chi square to compare the difference in Patient Global Impression of Improvement (PGI) between trainees [specialty (ST) and subspecialty (SST)] and consultants

	Consultant	Trainee	Marginal row totals
Improved	8594	1969	10,563
Not improved	359	95	454
Marginal column totals	8953	2064	11,017 (grand total)

Chi square statistic = 1.4922; p value = 0.22187 (not significant). This result was also nonsignificant when trainees were divided into specialty and subspecialty registrars

Applications of this information

It has been shown that it is possible to establish a "real life" complication rate range using the funnel plot calculated from the BSUG database. This can be used by individual clinicians to assess performance and give early indicators if their rates are above the upper limits of the range. Practice can then be adjusted to work towards lower complication rates. Long-term personal data is also reassuring if a clinician experiences a short run of complications, so previous data can be examined and the clinician can be confident that it was a cluster of complications. Future work will evaluate the principles of clustering and examine ways to segment the analysis to aid separating sporadic events from poor practice. This information can be used as evidence in appraisals, and annualising or segmenting data may help explain adverse events. If the complication rate is low, a clinician can be justified in operating on more complicated or difficult cases; if there is a higher complication rate, then referral of difficult cases to a specialist centre should be considered. It would be beneficial to identify units where there is a low complication or high success rate and learn from them. Surgical expertise is likely to be important, but patient preparation, selection and aftercare also plays a part. Sequential data entry should be encouraged to allow up-to-date and accurate

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information to be given to patients. This type of database with massive numbers also allows for slight differences in practices to be examined, for which it would not be appropriate to set up a clinical trial to see if a particular small change produces a beneficial effect in patients.

One of the strengths of this database is that data sets for many units are large enough to be shown to the patient, in real time, on the computer, in graph form, in the consultation, by selecting the appropriate setting in the database. It is our experience that patients are greatly reassured by seeing "their" surgeons' data over and above the information leaflets and that this gives patients the reassurance that their surgeon is practising within safe ranges compared with colleagues across the country. This is hugely useful to facilitate informed consent, particularly more so in urogynaecology where the non-life-saving, elective nature of the operations make consent even more important. Data from the database can also be included in bespoke patient information leaflets where general BSUG or IUGA leaflets can be used, which also contain unit-specific complication and success rates. Measuring outcomes and complications of retropubic tapes gives the potential to perform individual patient risk stratification for success or complications by entering body mass index (BMI), age [7], urodynamic studies (UDS), previous surgery and concomitant surgery—just as thoracic surgeons do [13]. We hope that the format of this analysis will be the first of many to examine medical practice and help to raise its standards.

Limitations of this study

Patient-reported outcomes depend on the expectation of both the patient and the surgeon and the degree of mismatch or miscommunication there is between the two. It is much more subjective and nuanced than a physical measurement of SUI. We felt it was more appropriate to use this form of study than a clinical objective measure, as the aim of incontinence operations is to improve quality of life.

Risk adjustment was not possible regarding BMI, age [7], UDS, previous surgery, concomitant surgery, fitness and other patient characteristics. Some centres regularly perform more complex cases, and it would therefore be expected that their complication rates would be higher.

Data bias may occur due to incomplete data, which is multifactorial: Firstly, it depends on data being entered honestly. Secondly, data from an entire centre may not be entered due to a general aversion to the BSUG database or cases are undertaken by a urologist who does not use the database. Thirdly, specific operations may not be entered due to lack of time or employees or a reluctance to enter a poor outcome; however, our data does not suggest this. Lastly, individual fields of a patient's operation may not be completed, again due to the mentioned reasons. Only a mandatory database would remove this bias, such as has been achieved by the Danish urogynaecologists (http://dugabase.dk). This could only feasibly be achieved by the input of the government or other licensing body. An option would be to only accredit units entering above a certain percentage of data into the database—in a similar fashion to the thoracic surgeons [13].

Care needs to be taken not to allow inaccurate data to be published to the general public, as it will be misinterpreted.

Conclusion

- Retropubic tapes are successful in treating SUI and have high rates of patient satisfaction.
- The real-time BSUG database suggests a real-life bladder perforation rate of 3.5 % overall, which is lower than previously reported studies.
- Other "standard" complication rates are low.
- There are significantly higher rates of bladder perforation for trainees than consultants.
- The perforation rate varies by centre, and while this is likely due to a number of variables, a major factor is the proportion of procedures performed by trainees.
- Our study confirms that perforation rate is a valid surrogate for quality, with a small but measurable difference. There is a statistically significant difference in the PGI and cure/improvement of SUI between patients who did and did not incur a perforation.

The increasing popularity of the BSUG database represents a fantastic resource of "real patient data". We suggest that all urogynaecological operations and their outcomes be recorded on this. The data has been collected, and we have a responsibility to analyse those data to improve patient care. We encourage colleagues to support the IUGA database initiative.

Acknowledgements BSUG database committee; Paul Moran; Phil Assassa.

Compliance with ethical standards

Financial disclaimers/Conflicts of interest PTH has acted as a speak er and advisor to Boston Scientific, Astellas, Allergan and SEP Pharma. He has had assistance to attend meetings from Astellas and SEP

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GYNECOLOGY

The effect of body mass index on retropubic midurethral slings

Check for updates

Fiona Bach, MBChB, BSc, MRCOG; Simon Hill, MB, BS, FRCOG, MFFP; Philip Toozs-Hobson, MBBS, ASM, FRCOG, MD

BACKGROUND: Analyzing surgical databases uses "real-life" outcomes rather than highly selected cases from randomized controlled trials. Retropubic midurethral slings are a highly effective surgical treatment for stress urinary incontinence; however, if modifiable patient characteristics alter outcomes, thereby rendering treatments less effective, patients should be informed and given the opportunity to change that characteristic.

OBJECTIVE: The aim of this study was to evaluate the effect of body mass index on patient-reported outcome measures by analyzing midurethral slings from the British Society of Urogynaecology database.

MATERIALS AND METHODS: The British Society of Urogynaecology approved analysis of 11,859 anonymized midurethral slings from 2007 to 2016. The primary outcome of this retrospective cohort study was to assess how body mass index affects patient-reported outcome measures. Outcomes were assessed at 6 weeks, 3 months, 6 months, or 12 months after surgery, depending on local arrangements. Outcomes were compared by body mass index groups using χ^2 tests.

RESULTS: As BMI increased, Patient Global Impression of Improvement (PGI-I) scores declined. Women with a normal body mass index (18 to <25) reported feeling better in 91.6% of cases compared to lower rates in BMI groups >30 (87.7−72%) ($P < .001$). Patient-reported outcome measures for stress urinary incontinence inversely correlated with body mass index, with 97% of women with normal body mass index stating that they were cured/improved compared to women in higher body mass index groups (84−94%) reporting lower rates ($P < .005$). Patient-reported outcome measures for overactive bladder show that as body mass index increases, patients reported higher rates of worsening symptoms ($P < .05$). There were higher rates of perforation at the low and high extremes of body mass index.

CONCLUSION: Our results suggest increased body mass index is associated with poorer outcomes after midurethral sling surgery, and that patients should be given the opportunity to change their body mass index. These data could help to develop a model to predict personalized success and complication rates, which may improve shared decision making and give an impetus to modify characteristics to improve outcomes.

Key Words: bladder perforation, BMI, midurethral sling, obesity, patient-reported outcomes, stress urinary incontinence

In the past 2 decades (1993 2014), in England, the prevalence of obesity in adults has risen from 14.9% to 25.6%, and continues to increase.[1] The association between stress urinary incontinence (SUI) and increasing body mass index (BMI) is well recognized.[2 4] Studies have shown that weight loss improves SUI and may render surgery unnecessary.[5] Obesity is a modifiable patient characteristic, so it is vital that clinicians are able to inform patients about its impact on SUI surgery, providing appropriate information and thus encouraging and empowering lifestyle change.

Midurethral slings (MUS) are a highly effective surgical treatment for SUI.[6] Surgical complications exist for all procedures; however the risk of failure to improve symptoms or to cause additional bothersome symptoms is particularly pertinent for reconstructive surgery, for which the functional outcome is of paramount importance. Recent controversy regarding the use of synthetic materials in pelvic floor surgery means that not only do patients expect to be better informed of these risks, and indeed alternative treatments, but medico-legally (in the United Kingdom), the Montgomery ruling has cemented the importance of this discussion as part of the consent process.[7] Of relevance, and often cited in litigation, is the argument that had the patients been informed of the risks, they would not have agreed to undergo surgery, and it has been shown that if patients receive detailed counseling, they are likely to opt for less invasive treatments.[8]

A BMI of >40 or >35 in combination with comorbidities such as cardiac, respiratory, or metabolic diseases is associated with increased surgical morbidity such as infection, thromboembolism, bleeding, organ damage, surgical difficulty, or even the requirement to abandon surgery. Anesthetic difficulties include cannulation, airway and ventilation, analgesia, nausea and vomiting, and moving patients.[9] Indeed some surgical centers have developed guidelines, which restrict surgical intervention for non−life-threatening conditions in patients with morbid obesity.[10] This may be driven in part by commissioners rejecting referrals[11] for surgery in patients with high BMI. If surgery is to be offered to these high-risk groups, the additional risks must be highlighted.

The British Society of Urogynaecology (BSUG) database is a secure database available to BSUG members through an NHS (N3 compliant) computer and is increasingly popular with urogynecologists. Preoperative patient characteristics are collected including age, BMI, and urodynamic diagnosis. The operation is recorded including intraoperative complications. Follow-up is then entered at a later date, which includes any postoperative complications and the

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AJOG at a Glance

Why was this study conducted?

The study was conducted because we wanted to establish the effect of body mass index on patient-reported outcomes of midurethral slings and because the use of slings in the severely obese population has not been studied on a large scale.

Key findings

Patients who are severely obese have poorer overall outcomes following midurethral slings. They are also more likely to develop symptoms of overactive bladder, which may explain the poorer global impression of improvement.

What does this add to what is known?

Other studies were limited by the numbers of patients in the severely obese categories and so are not relevant to the Western populations of today.

patient-reported outcome. Use of the database is recommended by several bodies, including National Institute for Health and Care Excellence and National Health Service England[12 14] and is a tool to measure "real-life" success rates and complication rates rather than using highly selected cases from randomized controlled trials and meta-analyses. Analysis of the data entered may assist not only with patient counseling and individual risk assessments but also with resource use, procurement, and best practice evaluation. Information can also be used at a personal level in appraisals or at a national level to identify benchmarks for appropriate practice.

The aim of this study was to use the BSUG database to examine the impact of BMI on patient-reported outcome measures (PROMs) and complication rates following an MUS.

Materials and Methods

Ethical approval for this study was not required, because individual centers using the database are required to be compliant with UK Caldicott Guardian (data protection) regulations. Patients give consent to their anonymized data being used for analysis.

TABLE 1
Participant characteristics, by BMI group

BMI	18 to <25	25 to <30	30 to <35	35 to <40	40 to <45	45 to <50
Age at operation, y (n = 11,572)						
18 to <50	1648 57%	2075 48%	1306 47%	589 50%	159 48%	41 45%
50 to <75	1137 39%	2045 47%	1345 49%	553 47%	163 49%	49 53%
75 to 100	103 4%	191 4%	119 4%	39 3%	8 2%	2 2%
Total	2888	4311	2770	1181	330	92
Preoperative urodynamic diagnosis (n =10,959)						
USI	2245 82.1%	3263 80.1%	2021 76.8%	825 73.8%	230 73.0%	62 72.1%
USI and voiding dysfunction	63 2.3%	106 2.6%	69 2.6%	30 2.7%	6 1.9%	4 4.7%
Mixed	292 10.7%	547 13.4%	438 16.6%	235 21.0%	70 22.2%	18 20.9%
Mixed and voiding dysfunction	10 0.4%	14 0.3%	19 0.7%	5 0.4%	4 1.3%	0 0.0%
DOA	11 0.4%	22 0.5%	13 0.5%	7 0.6%	1 0.3%	1 1.2%
Normal	111 4.1%	118 2.9%	70 2.7%	16 1.4%	4 1.3%	1 1.2%
Voiding dysfunction	2 0.1%	3 0.1%	3 0.1%	0 0.0%	0 0.0%	0 0.0%
Total	2734	4073	2633	1118	315	86
Grade of operator (n = 11,725)						

Bach et al. Effect of body mass index on sling outcomes. Am J Obstet Gynecol 2019. *(continued)*

TABLE 1
Participant characteristics, by BMI group *(continued)*

BMI	18 to <25	25 to <30	30 to <35	35 to <40	40 to <45	45 to <50
Consultant	2298 78.8%	3376 77.3%	2135 75.9%	915 76.3%	273 81.7%	77 83.7%
Associate Specialist	5 0.2%	21 0.5%	18 0.6%	9 0.8%	1 0.3%	0 0.0%
Subspecialty Trainee (SST)	187 6.4%	299 6.8%	192 6.8%	86 7.2%	16 4.8%	3 3.3%
Staff grade	37 1.3%	48 1.1%	43 1.5%	13 1.1%	6 1.8%	1 1.1%
Speciality Trainee (ST)	357 12.2%	564 12.9%	399 14.2%	160 13.3%	36 10.8%	10 10.9%
FTSTA	1 0.0%	1 0.0%	1 0.0%	0 0.0%	1 0.3%	0 0.0%
Other	33 1.1%	58 1.3%	26 0.9%	17 1.4%	1 0.3%	1 1.1%
Total	2918	4367	2814	1200	334	92

BMI, body mass index; *DOA*, detrusor overactivity; *FTSTA*, fixed term specialty training appointment; *SST*, subspecialty trainee; *ST*, specialty trainee; *USI*, urodynamic stress incontinence.
Bach et al. Effect of body mass index on sling outcomes. Am J Obstet Gynecol 2019.

Authorization was requested from BSUG to analyze data for patients who underwent the procedures with Mid-urethral Sling-Tension Free Vaginal Tape (MUS-TVT) (Ethicon Gynaecare, Somerville, NJ) or Advantage and Advantage Fit (Boston Scientific, Boston, MA) from January 1, 2007, until January 27, 2016. The application was approved in a 2-stage process initially by the BSUG Research Committee and was subsequently ratified by the BSUG Database Committee. Individual patients, doctors, and surgical centers cannot be identified due to anonymization of all data at source prior to release to the requesting team.

The primary outcome measure was to assess the effect of BMI on Patient Global Impression of Improvement (PGI-I) for incontinence. Secondary measures were SUI symptoms, OAB symptoms, bladder perforation, and short-term complications.

Follow-up of patients varied between 6 weeks and 12 months, depending on individual unit practice. A variety of methods are used to gather the specific patient-reported outcome measures, including outpatient clinics, postal questionnaires, telephone appointment, online questionnaires, with general practitioners or other individual preference according to custom at the place of surgery.

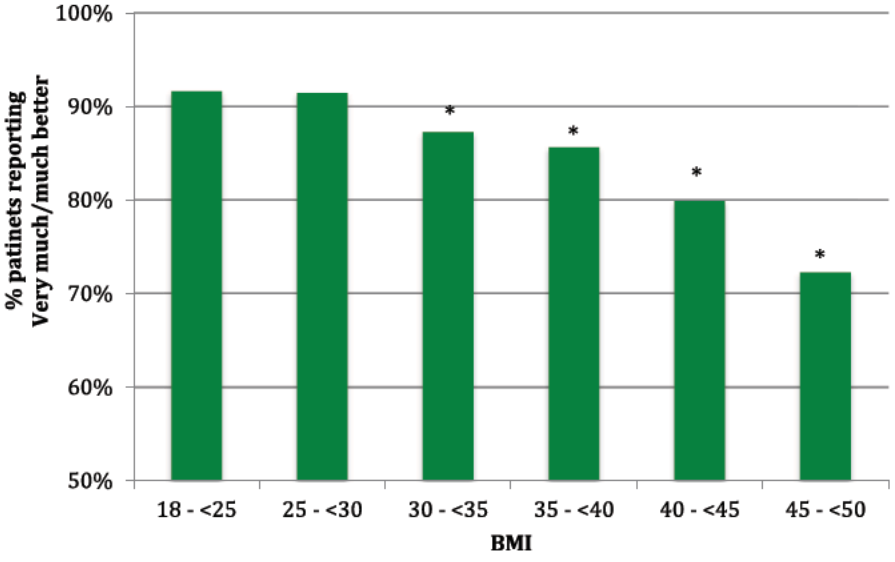
Overall outcome was measured in a standardized fashion using the patient-reported measure of PGI-I as a validated tool.[15] This is a 7-point scale of "Very Much Better, Much Better, A Little Better, No Change, A Little Worse, Much Worse, or Very Much Worse," and patients are asked to give their assessment of overall impression. For analysis, success was defined as "Very Much Better + Much Better.". Assessment of change in SUI and overactive bladder (OAB) were recorded at follow-up, and patients were questioned as to whether the symptoms

TABLE 2
Timing of postoperative assessment by body mass index (BMI) groups after midurethral sling surgery (n = 7778)

BMI	6 wk	3 mo	6 mo	12 mo
18 to <25	27%	37%	33%	4%
25 to <30	24%	39%	33%	4%
30 to <35	23%	39%	34%	4%
35 to <40	24%	36%	37%	3%
40 to <45	27%	30%	40%	4%
45 to <50	22%	21%	48%	9%

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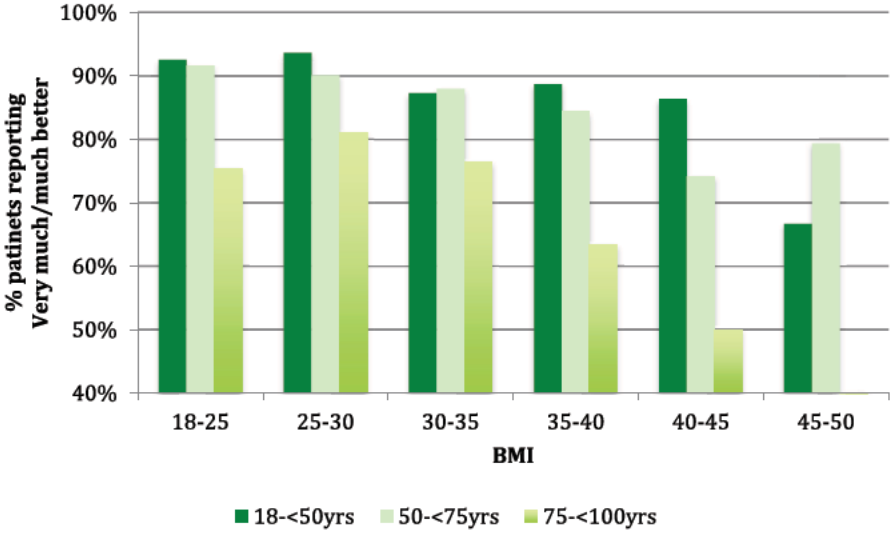
FIGURE 1
Body mass index (BMI) and Patient Global Impression of Improvement (PGI-I) for incontinence (n = 7429). Percentage of patients reporting very much or much better outcomes, by BMI group. *$P < .05$ compared to normal BMI group (18 to <25)



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were "Cured, Improved, No change, Worse, New Symptom or Never Present."[16,17] Outcomes were compared by BMI groups overall and stratified by important clinical factors using χ^2 tests. Excel (Microsoft Corp., Redmond, WA) and STATA (StataCorp, College Station, TX) software were used. *P* values <.05 were considered statistically significant.

FIGURE 2
Body mass index (BMI) and Patient Global Impression of Improvement (PGI-I) for incontinence, by age (n = 7267). Percentage of patients reporting very much or much better outcomes by BMI group, split by age



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Results

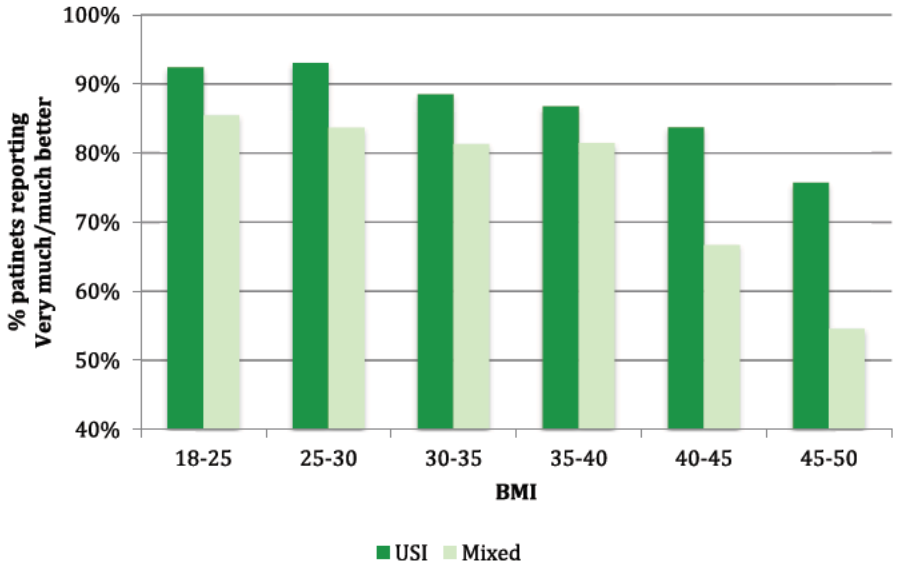
A total of 18,763 primary MUS procedures (of the aforementioned devices) were entered onto the database from 124 centers. The number of MUS entered per center ranged from 1 to 1721, with a median of 39. A total of 11,859 patients had BMI recorded, with the remaining 6904 either without a BMI entered or an invalid entry. BMI groups contained the following numbers of patients: BMI 15 to <18 had 13 patients (0.11%), 18 to <25 had 2943 (24.82%), 25 to <30 has 4401 (37.11%), 30 to <35 had 2838 (23.93%), 35 to <40 had 1209 (10.20%), 40 to <45 had 338 (2.85%), 45 to <50 had 92 (0.78%), and 50 to <65 had 24 (0.20%). Of the 11,859 cases with BMI data, 7436 had PGI-I data, 7398 cases reported PROM, and 11,816 recorded the presence or absence of bladder perforation.

The population data (Table 1) show that, in this group, patients with a lower BMI tended to be younger; that as BMI increased, the percentage of patients with mixed results on urodynamic studies (UDS) increased; and that patients with a higher BMI were more likely to be operated on by a consultant. Follow-up intervals are shown in Table 2.

Global Impression of Improvement

A decline in PGI-I is seen with rising BMI, with a significantly greater success rate in the group of patients with a normal BMI (18 to <25) compared to the groups of patients with BMI >30 ($P < .001$) (Figure 1, n = 7429). As previously mentioned, when studying the patient characteristics, patients with a BMI of 18–25 tend to be younger, so the population was divided into age groups; and the difference with BMI still remained (Figure 2, n = 7267). Also, because there is potentially a difference with UDS because of patients with a higher BMI being more likely to have a diagnosis of mixed urinary incontinence, the data were split to look at urodynamic stress incontinence (USI) and mixed difference in outcomes of

FIGURE 3
Body mass index (BMI) and Patient Global Impression of Improvement (PGI-I) for incontinence, by urodynamic studies (UDS) (n = 6530). Percentage of patients reporting very much/much better outcomes by BMI group split by urodynamic diagnosis



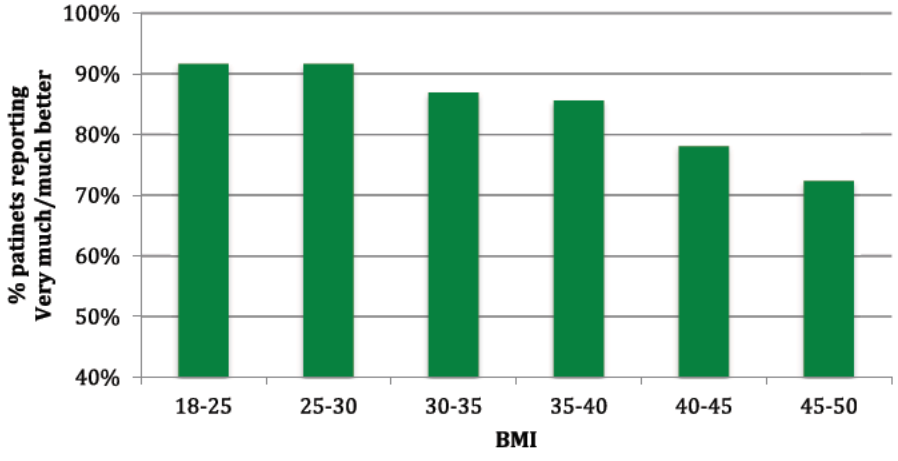
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different BMIs. The differences still remained (Figure 3, n = 6530). Because of the relative lack of trainees operating on patients with higher BMI, the data were analyzed again only for consultants performing the operations. The difference still remained (Figure 4, n = 5793).

Change in SUI Symptoms

The percentage of patients reporting cure or improvement of SUI symptoms correlated inversely with rising BMI. A significantly lower proportion of women in the BMI groups >35 stated that they were cured or improved compared to patients with a normal BMI (35–40, $P = .004$; 40–45, $P = .005$; and 45–50, $P < .001$) (Figure 5, n = 7176).

FIGURE 4
Body mass index (BMI) and Patient Global Impression of Improvement PGI-I for incontinence, for procedures performed by consultants (n = 5793). Percentage of patients reporting very much/much better, by BMI, for procedures performed only by consultants



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Change in OAB Symptoms

Our analysis agrees that OAB symptoms are more common in women with increasing BMI[18] (Table 1) and the falling percentage of patients reporting "OAB symptoms never present" with increasing BMI in our series (Figure 6, n = 7123).

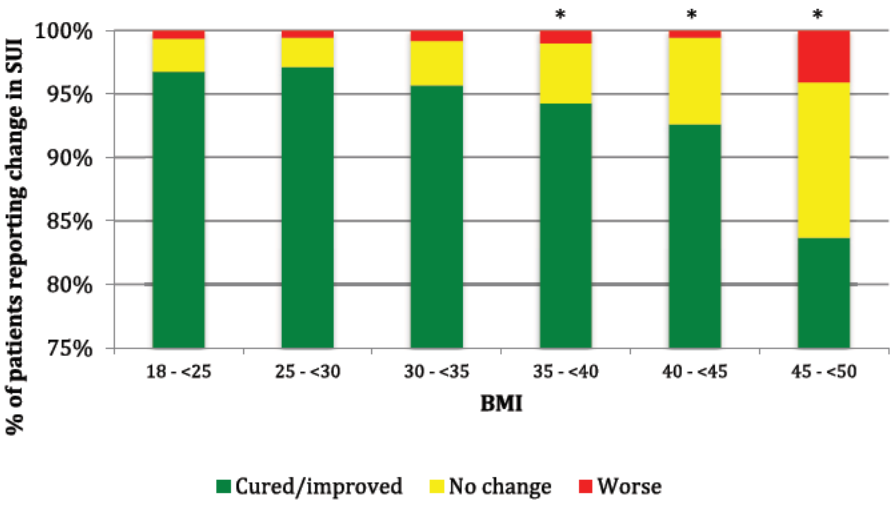
PROMs for change in OAB symptoms showed that, as BMI increased, a higher proportion of patients reported worsening symptoms (Figure 7, n = 4187). For the group with BMI of 18–25, 8.45% become worse vs 65.8% being cured or improved, compared to the group with BMI of 45–50, of whom 21.9% became worse vs 53.7% being cured or improved. Thus, although overall patients are likely to see an improvement in OAB symptoms following an MUS, the ratio of improvement to worsening is poorer with higher BMI. To state it another way, with a BMI of 18–25, a patient's OAB symptoms are nearly 8 (7.8) times more likely to be cured or improved than to deteriorate, whereas with a BMI of 45–50 a patient's symptoms are only 2.5 times more likely to be cured or to improve compared to worsening.

When only patients with no preoperative OAB symptoms were studied, the rate of patient-reported "new OAB" cases increased with increasing BMI (Figure 8, n = 2936). There were no new cases of OAB in the group with BMI 45–50, which does not fit with the pattern; however, this may be because there were only 10 cases for analysis in this group, as the majority of patients (n = 41) had pre-existing symptoms that excluded them from this subanalysis.

Perforation

There were higher rates of perforation at the low and high extremes of BMI. There were significantly fewer perforations

FIGURE 5
Body mass index (BMI) and change in stress urinary incontinence (SUI) symptoms (n = 7176). Percentage of patients reporting different outcomes of SUI symptoms by BMI group. *$P < .05$ compared to normal group with normal BMI (18 to <25)



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with the groups with BMI 25 to <30 ($P = .032$), 30 to <35 ($P < .001$), and 35 to <40 ($P < .001$) compared to 18 to <25, although it is noteworthy that this difference was not observed in the groups with BMI of 40–45 ($P = .057$) or 45–50 ($P = .54$) (Figure 9, n = 11,816). This difference is borne out when consultants and trainees were separated, although the effect with trainees was much greater (Table 3).

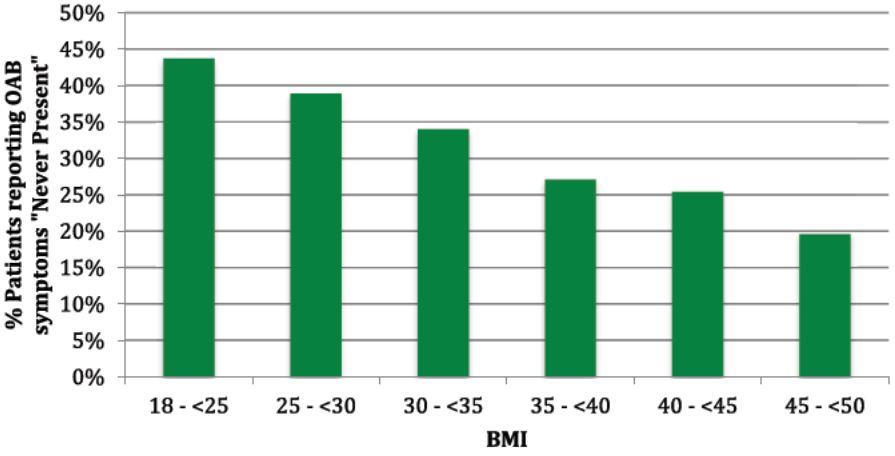
Comment

Although the overall percentage of patients who report on PGI-I that they are "better" following an MUS is high (95.8%),[19] women with a greater BMI are less likely to report a PGI-I of "very much better/much better" and cure/improvement of SUI symptoms. In addition, not only does a higher BMI suggest a higher preoperative rate of OAB and mixed UDS, there is a greater chance that OAB symptoms will develop or worsen postoperatively. These outcomes may all be interrelated with the presence or worsening of OAB symptoms, leading to poorer results with respect to PGI-I and SUI PROM. Ultimately, there is a complex construct of different symptom combinations, which will vary from patient to patient.

A recent paper using data from the DUGAbase[20] found that there was no difference in subjective outcome between the different BMI group; however, the highest BMI category in that study was ">35," whereas the data in this study were divided into 35–40, 40–45, and 45–50, meaning that differences can be identified in the much-higher BMI groups. Interestingly, researchers in the other study did find that there was a nonsignificant higher risk of reoperation in patients with a BMI of >35. Other studies also have similar limitations and therefore did not examine the higher BMI categories.[21 23] This means that our study findings may be more relevant to the current Western, including American, populations in view of rising BMI in these populations.[24]

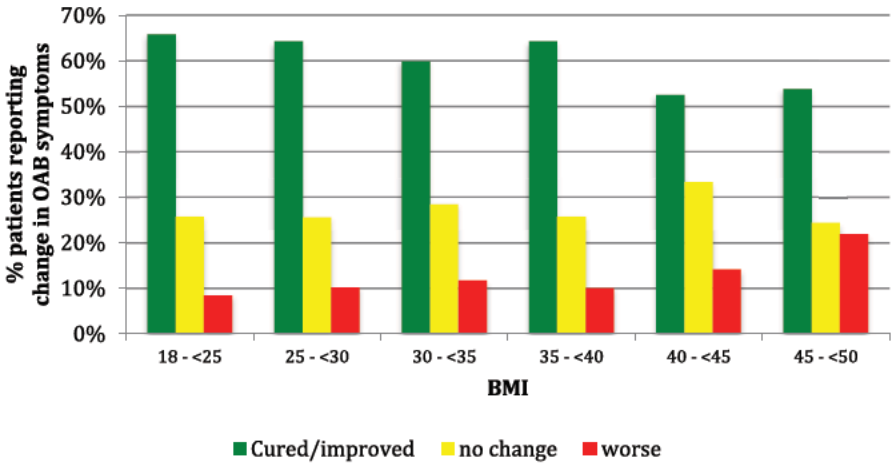
The bladder perforation rate graph is interesting and may be explained on the basis that as the BMI increases, there is an optimal amount of protective fat around the bladder, thereby reducing the rate of injury. Once the BMI becomes very high, however, the anatomical landmarks become distorted, and it may become more difficult to negotiate a fixed curved needle behind the symphysis pubis. The comparative data for perforation at different BMI groups between consultants and trainees is very interesting, with a dampening of the effect of BMI on perforation with experience. Again, a previous paper did not find this to be the case; however the highest group in this paper was patients with a BMI of 30.[21]

FIGURE 6
Overactive bladder (OAB) symptoms "never present," by body mass index (BMI) (n = 7123). Percentage of patients reporting that they had never had OAB symptoms, by BMI



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FIGURE 7
Body mass index (BMI) and change in preoperative overactive bladder (OAB) symptoms (n = 4187). Percentage of patients experiencing change in their OAB symptoms, by BMI



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Study Strengths

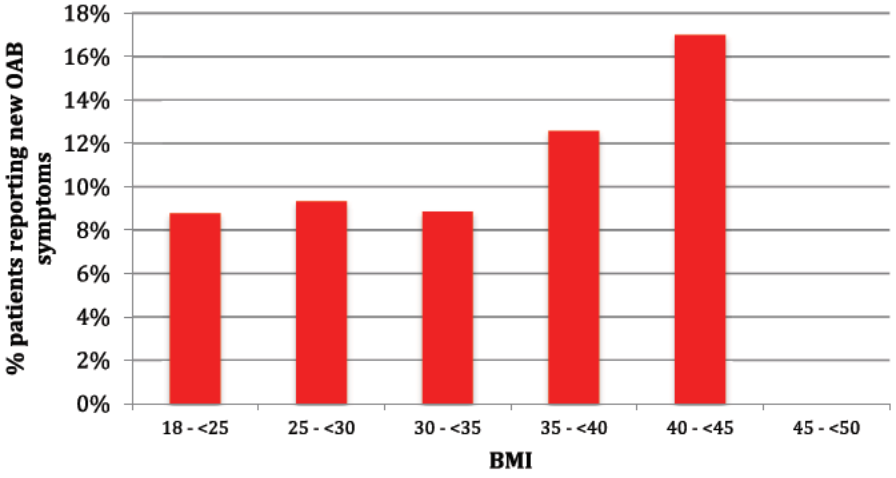
The major strength of this established database and this study is the large number of "real-life" outcomes from a wide range of different centers and surgeons, rather than the more restrictive patient groups included in randomized controlled trials. The comparison to the other papers highlights the huge benefit of a population-based database, as the numbers are so large that the "smaller" groups of patients still contain large amounts of patients.

Study Limitations

The BSUG database contains a variety of timescales and methods of follow-up based on individual preference, and to mandate a change to this would be inappropriate.

Missing data comprise an important limitation. Use of the database is mandatory only for those centers who are accredited by BSUG, but many other, nonaccredited centers do use it. There may be individual data, patients, or whole units that are not included, either because clinicians or patients do not want to be involved, are too busy, or are not inclined to report complications.[25] Missing data are common in large registries, and analyses of PGI-I and PROM data were performed in ~40% of the patient cases in the registry.

FIGURE 8
Body mass index (BMI) and new overactive bladder (OAB) symptoms (n = 2936). Percentage of patients experiencing new OAB symptoms, by BMI



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Future Work

With the current uncertainty about the future of the MUS, it will be interesting to run this analysis on the alternatives, as it is likely that the complications will be far greater in the obese population and that, if the MUS is unavailable, the viable management options for USI in the obese population will therefore be dramatically reduced.

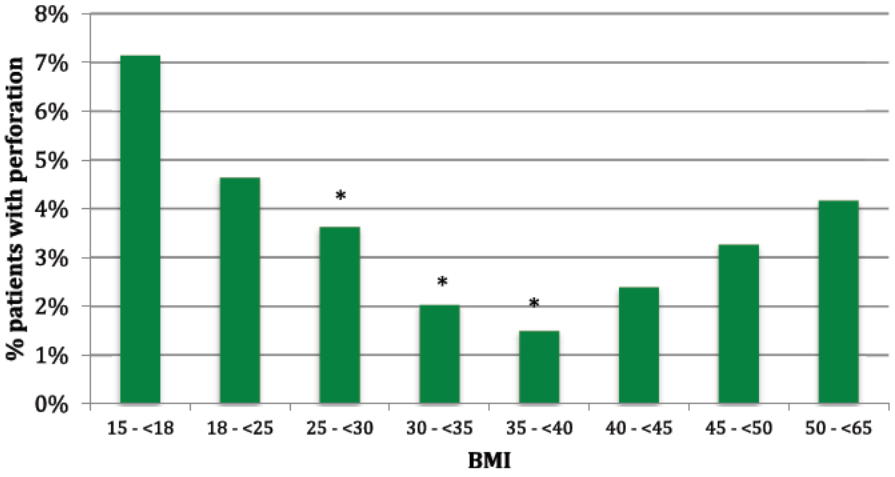
Identification of modifiable characteristics that have an impact on the likelihood of success and the risk of complications from MUS and all surgeries for USI[26] could be combined to create a computerized algorithm to allow patients to make an informed choice as to whether or not to proceed with surgery, or to defer intervention while undertaking lifestyle changes. The database can also be developed to be used for benchmarking for individual clinicians or centers.

Final Comments

This study highlights the value of recording demographics, procedural data, and patient outcomes on a national database and how this could be used to aid decision making in the future. Subsequent analysis—in this case, the effect of BMI—can inform a broad range of health care professionals in respect to the extent of risk of an intervention, which can then be translated into meaningful, individualized assessment. Incorporation of such data into the shared decision-making process is likely to result in greater patient satisfaction, through improved understanding and awareness of risk.

FIGURE 9

Body mass index (BMI) and perforation rate (n = 11,816). Percentage of patients who experienced a bladder perforation, by BMI. *$P < .05$ compared to group with normal BMI (18 to <25)



Bach et al. Effect of body mass index on sling outcomes. Am J Obstet Gynecol 2019.

The information in this analysis should not preclude patients with high BMI from receiving interventions; however, we would reinforce that individualized patient counseling is of vital importance prior to an MUS, and that overweight patients should be made aware of the possibility of a lower success rate. They should also be advised that rates of pre-existing SUI and OAB are higher in patients with higher BMI.[18,27] BMI is modifiable and, if reduced, surgery may be rendered unnecessary; if it is still required, then logically the outcome should be more successful. However, patients must be informed of the individual risks, and, in the context of informed consent, these lifestyle alternatives should also be personalized to comply with the Montgomery ruling.[28]

TABLE 3

Percentage of bladder perforation by surgeon type (consultants, n = 9049; trainees, n = 2301)

BMI	Consultant	Trainee
18 to <25	3.3%	10.1%
25 to <30	2.0%	9.9%
30 to <35	1.5%	4.1%
35 to <40	1.2%	1.6%
40 to <45	2.2%	0.0% (n=0)
45 to <50	1.3%	15.4%

BMI, body mass index.

Bach et al. Effect of body mass index on sling outcomes. Am J Obstet Gynecol 2019.

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An analysis of 1386 periurethral bulking procedures with comparison to 18,763 retropubic tapes

Fiona Bach and Philip Toozs-Hobson; on behalf of the BSUG database users

Abstract

Objective: To use British Society of Urogynaecology surgical database to evaluate periurethral bulking agents and retropubic tapes.

Study design: Permission was granted to analyse 1386 periurethral bulking agents and 18,763 retropubic tapes. The primary outcome measure was patient reported global impression of improvement for incontinence with secondary outcomes of change in symptoms of stress incontinence, overactive bladder and complications.

Results: Patients undergoing periurethral bulking agents were older than retropubic tapes (mean 59.4 vs. 52.3 years). Urodynamic stress incontinence was the commonest urodynamic diagnosis (periurethral bulking agents 67%, retropubic tapes 77%) but there was a higher proportion of complex diagnoses in the periurethral bulking agents group. 59.2% patients reported 'very much/much better' on patient reported global impression of improvement for incontinence for periurethral bulking agents compared to 91% for retropubic tapes; 28% patients felt their symptoms of stress incontinence were cured following periurethral bulking agents compared to 77.6% for retropubic tapes and 0.8% developed de novo overactive bladder following periurethral bulking agents compared to 4% with retropubic tapes. There was no difference in outcomes when using periurethral bulking agents as a primary or secondary procedure. There were no intraoperative complications with periurethral bulking agents and fewer post-operative complications compared to retropubic tapes (3.6%).

Conclusion: Patient reported success of periurethral bulking agents is lower than retropubic tapes but this is offset by minimal complications despite being an older, more complex patient group. Periurethral bulking agents do appear equally efficacious as a secondary procedure. Information derived from databases can be used during counselling to allow clinicians to demonstrate their own success and complication rates to ensure patients make an informed choice. Patient choice is paramount so all options should be included in full counselling.

Keywords

Bulking agent, database, retropubic tape, stress urinary incontinence

Introduction

Periurethral bulking agents (PUB) are a treatment for stress urinary incontinence (SUI) and are included as an option in the UK National Institute for Health and Care Excellence (NICE) guidelines only if alternative surgical procedures are not suitable or acceptable to the woman.[1] Retropubic tapes (RPT) have been a very popular option for SUI but with concerns about the safety profile of all products containing mesh, other options are now increasingly considered important. The aim of this study was to use the British Society of Urogynaecology (BSUG) database to gain insight into national use of PUB including patient characteristics, complications and efficacy and to compare these to RPT.

A systematic review looking at PUB found subjective success rates ranging from 66% to 89.7%[2] and

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found that objective success rates were less well documented than in studies about slings but ranged between 25% and 73%. The Cochrane review found that subjective cure rates for RPT up to 1 year is 71%–97%, from 1 to 5 years 77%–98% and in the longer term (>5 years) from 51% to 88%.[3] The objective cure rate for RPT was 87%. An on-going prospective, randomised controlled trial (RCT)[4] comparing Bulkamid to tension free vaginal tape (TVT) found that, on initial analysis at one year, the mean satisfaction visual analogue score (VAS) for TVT was 99 and was 85 for Bulkamid. There were more favourable objective outcomes for TVT with respect to negative cough test (95% vs. 66%) and combined negative cough and pad test (91% vs. 54%).[5] The complication rate was higher in the TVT group with only patients in the TVT group requiring re-operations.

A lower success rate, if coupled with a low complication rate, is not necessarily undesirable. A study looking at patient perspectives of PUB showed that women do not necessarily expect a complete cure for urinary incontinence, rather they want to improve and have reported that 'becoming dry was wishful thinking'[6] and as such, patient related outcomes or goals are increasingly important as part of the assessment of outcome. This study also found that this group of patients felt women should be informed about PUB when being counselled about surgical options for SUI.[6]

The BSUG database is a national secure database for BSUG members accessed through an NHS computer. There are over 140,000 operations recorded to date. Data are entered by the consultant, or deputy, at the time of the operation and again at each follow-up. Completion of the database is voluntary but recommended by NICE guidelines.[1]

Methods

This project formed a subset piece of work which was part of a larger study into outcomes from the BSUG database. Approval from BSUG was granted to analyse data for patients who underwent Bulkamid and Macroplastique (July 2007 to October 2016) and this was compared with a previous analysis of RPT.[7] Applications for data are assessed in a two-stage process, initially by the BSUG Research Committee and subsequently authorised by the BSUG Database Committee. All data are anonymised before release to ensure individual patients, doctors and surgical centres cannot be identified. Individual centres using the database are required to be compliant with UK Caldicott Guardian (Data protection) regulations so additional ethical approval was not required. Patients individually grant consent to their anonymised data being used for analysis.

The primary outcome measure was the validated Patient Reported Global Impression of Improvement (PGI-I).[8] The PGI-I is a patient reported outcome with a seven point scale of 'Very Much Better, Much Better, A Little Better, No Change, A Little Worse, Much Worse or Very Much Worse'. Success was defined as 'Very Much Better + Much Better'.

The secondary outcome measures were change in SUI symptoms, change in OAB symptoms, intra-operative complications, post-operative complications and length of hospital stay. Change in SUI and OAB symptoms from a patient perspective were recorded under the headings 'Cured, Improved, No change, Worse, New Symptom or Never Present' and this has been validated.[9] The post-operative complications included bladder, urethral, ureteric, bowel, vascular and neurological injury, blood loss >500 ml, blood transfusion, peri-operative thromboembolism and death. Analysis was performed using Excel and χ^2 test.

Follow-up of patients varied as per individual unit practice and were seen between 6 weeks and 12 months at outpatient clinics, by postal questionnaires, online, by assessment over the telephone or with the General Practitioner. When recorded, the commonest follow-up time was 3 months (56%) with 35% at 6 weeks and 9% at 6–12 months. The majority of follow-up was via an outpatient visit to the operating surgeons clinic (95%).

Results

A total of 1386 PUB and 18,763 RPT were identified from the database.

Patient characteristics

The mean age of patients undergoing RPT was 52.3 years (range 18–100) compared to 59.4 years (range 19–99) for PUB. There was a younger mean for primary PUB compared to repeat procedures (57.9 vs. 61.5 years). (No recorded age PUB: 56 (4%), RPT: 532 (3%). There is a peak around the menopause in RPT but the spread is much more even in PUB (Figure 1(a) and (b)).

Of the 1386 patients that had PUB, 1153 (83%) had pre-operative urodynamic diagnosis (UDS) outcome recorded on the database. The most frequent UDS for PUB was urodynamic stress incontinence (USI) (67.0%) and this is also true for RPT but with a higher percentage of 77.2% ($p < 0.001$). When the UDS is more complex PUB are used proportionately more than RPT (mixed UDS: 21.7% vs. 15.6% and voiding dysfunction: 4.9% vs. 2.5%) (Figure 2).

Of the 1386 PUB, 783 (56%) were a primary procedure and 539 (39%) had previously undergone

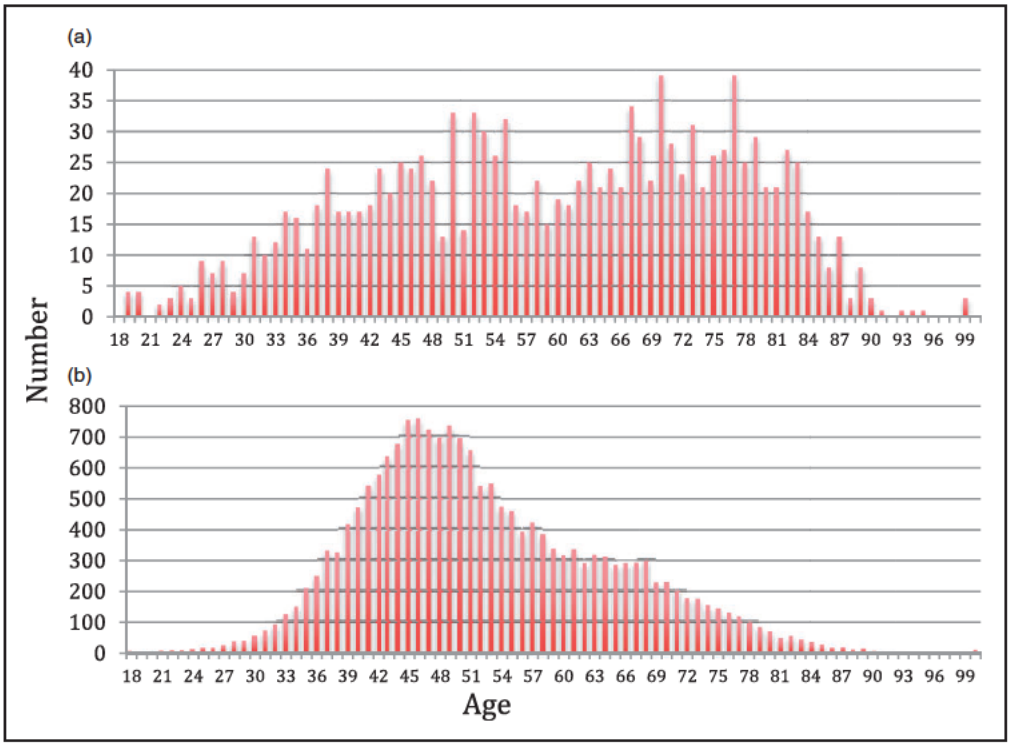


Figure 1. (a) Ages of all bulking procedures. (b) Ages of MUS as primary procedure.
Note: Please refer to the online version of the article to view the figures in colour.

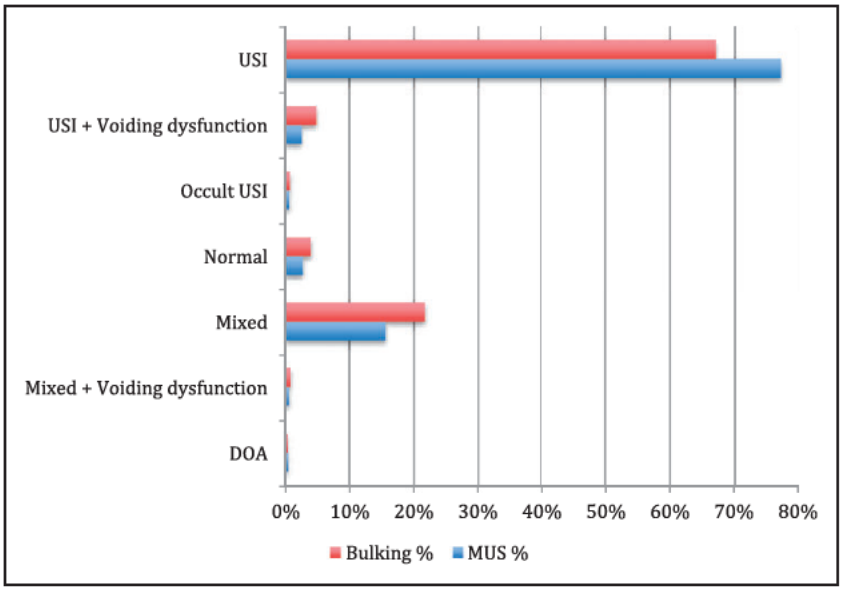


Figure 2. Distribution of UDS for bulking agents and MUS.
Note: Please refer to the online version of the article to view the figures in colour.

one or more procedure for SUI, 64 were unanswered (5%) (Table 1); 350 (64.9%) patients had had one previous procedure, 85 (15.8%) two previous procedures and 20 (3.7%) three, with incomplete data on 84 patients.

Patient reported global impression of improvement for incontinence

Of the 1386 PUB, 742 had data for PGI-I (53.5%) and 11,366 out of 18,763 RPT had these

data (60.6%). Of these, 91.0% of patients reported feeling 'very much better' and 'much better' on PGI-I following RPT compared to 59.2% for PUB (Figure 3) ($p \leq 0.01$)

Table 1. Previous SUI procedures performed prior to this bulking episode.

Previous surgery	Frequency
RPT/TVT A	168
Bulking agent	165
TOT/TVT O/TOT needleless	122
Colposuspension open	74
Single Incision tape/minisling	12
Anterior repair (AR) + BNB	11
Stamey procedure	11
Sling	10
MMK	6
Unrecorded	84

MMK: Marshall Marchetti Krantz procedure; TOT: transobturator tape.

Change in SUI symptom

Of the 1386 PUB, 664 had data for change in SUI (47.9%) and 10,685 out of 18,763 RPT had these data (57%).

Majority of the patients (77.6%) reported their symptoms of SUI are 'cured' following an RPT compared to 28% PUB ($p < 0.01$). And, 22.3% patients reported 'no change' in symptoms of SUI following PUB compared to 2.7% with RPT ($p < 0.01$) (Figure 4).

There is a similar efficacy between PUB being performed as a primary surgery or after a previous procedure for SUI (Figures 3 and 4) with no difference in the PGI-I ($p = 0.47$) or change in SUI outcome when looking at those patients that were cured ($p = 0.57$) or cured/improved ($p = 0.21$).

Of the 1386 PUB, 623 had data for change in OAB symptoms (44.9%) and 10,290 of the 18,763 RPT had these data (54.8%).

Fewer patients (0.8%) developed de novo OAB following a PUB compared to 3.8% following RPT.

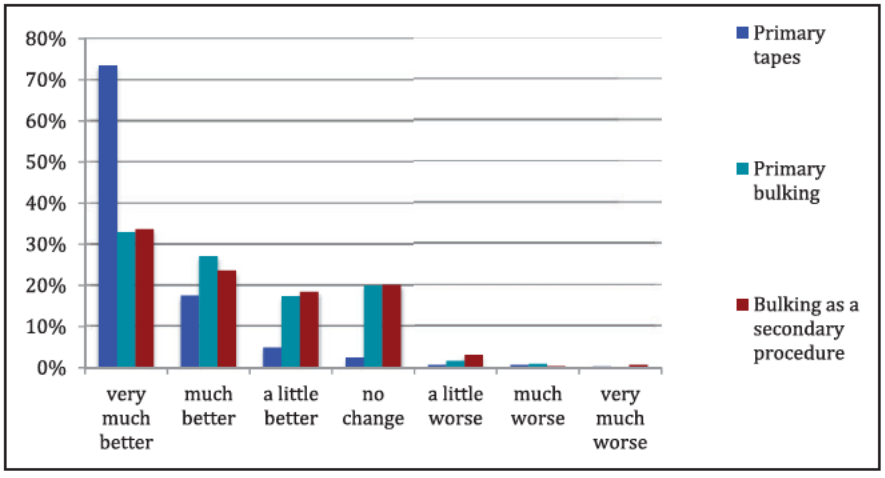


Figure 3. PGI I: primary tapes versus primary bulking vs bulking as a secondary procedure.
Note: Please refer to the online version of the article to view the figures in colour.

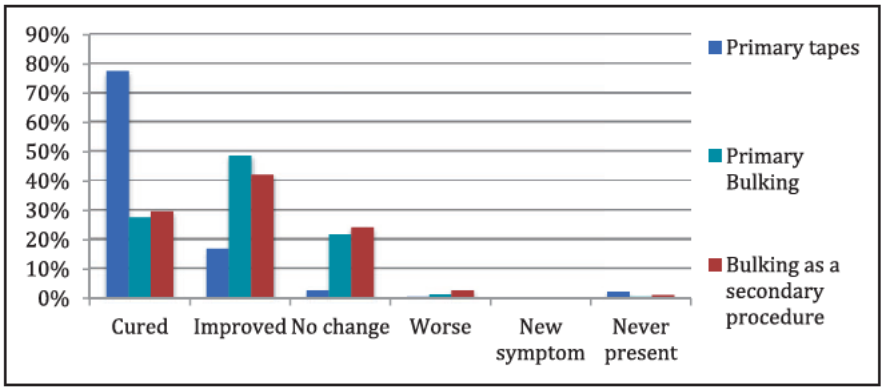


Figure 4. Change in SUI: primary tapes versus primary bulking versus bulking as a secondary procedure.
Note: Please refer to the online version of the article to view the figures in colour.

The chance of cure of OAB symptoms (Figure 5) is lower with PUB (5%) compared to RPT (15.8%) whereas the chance of improvement is similar (20.7% vs. 23.4%). Similarly to the SUI symptoms, a higher percentage of those patients having had a PUB saw no change in symptoms of OAB.

PGI-I and change in SUI symptoms are more likely to be positive in patients who have UDS that include

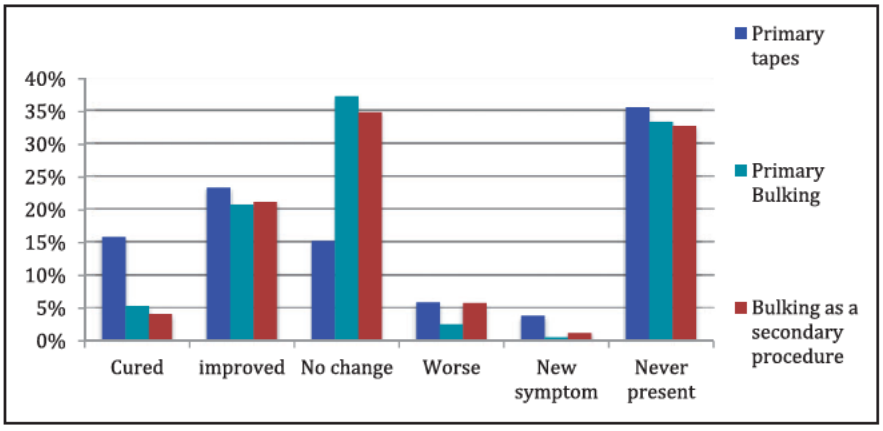


Figure 5. Change in OAB: primary tapes versus primary bulking versus bulking as a secondary procedure.
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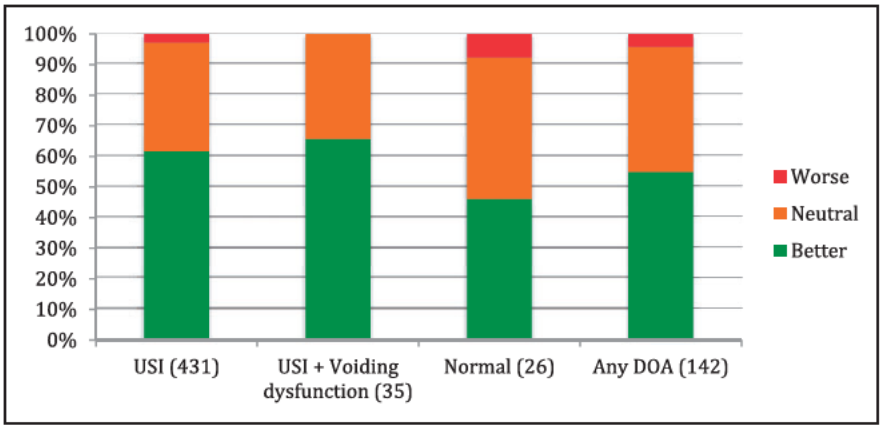


Figure 6. PGI I dependent on UDS: Bulking.
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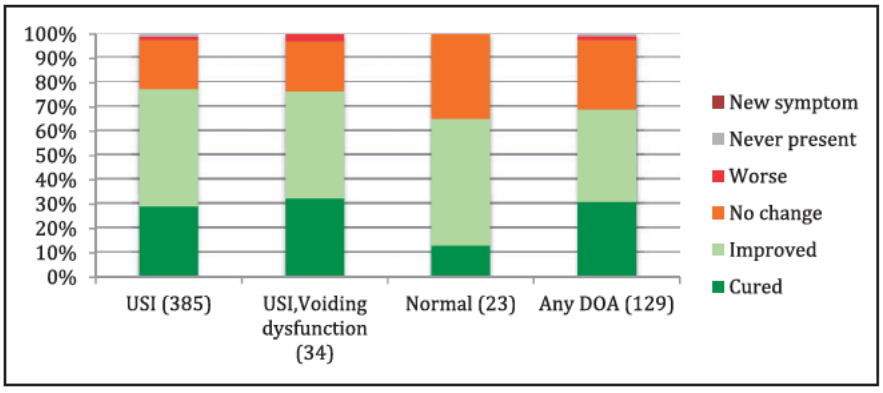


Figure 7. Change in SUI dependent on UDS: Bulking.
Note: Please refer to the online version of the article to view the figures in colour.

SUI (Figures 6 and 7) but this does not reach statistical significance ($p > 0.05$).

There were no intraoperative complications recorded during 973 PUB procedures when performed without concomitant surgery (unanswered 1.5%), compared to the following complications for the 12,689 RPT without concomitant surgery (unanswered 1%): 3.6% bladder perforation, 0.4% >500 ml blood loss, 0.14% urethral and 0.05% vascular injury (Table 2). RPT patients are more likely to return to theatre, be catheterised for >10 days and return/be readmitted to hospital within 30 days (Table 3).

Table 2. Complications for RPT with no concomitant surgery.

Complication	Frequency RPT
Bladder injury	3.59%
Vaginal button holing	0.54%
Blood loss > 500 ml	0.40%
Urethral injury	0.14%
Perioperative blood transfusion	0.06%
Vascular injury	0.05%
Perioperative thromboembolism	0.03%
Bowel injury	0.01%
Neurological injury	0.01%
Death	0.01%
Ureteric injury	0.00%

Initial hospital stay was short following the 973 PUB performed without concomitant surgery (unanswered 28%) with the majority (97.5%) staying for 1 day or less and 19% of procedures being performed as an outpatient. Fewer patients stayed for 2 or more days with PUB compared to RPT (15%) ($p < 0.05$).

With the UK mesh pause, dramatic differences have been seen in the procedures being performed for SUI as seen in Figure 8. This compares the breakdown of SUI surgery in 2017 compared to the 6 months following the pause (1 August 2018 to 31 January 2019) which indicates lower absolute numbers 3424 versus 1374 (6 months), but also a huge percentage rise in PUB, accounting for 64% of all surgeries performed, which makes this information very relevant to patients and clinicians.

Discussion

PUB have traditionally been viewed as a salvage or last resort treatment or as an acceptable minimal intervention option for elderly or medically unfit patients, unable to undergo a larger or more invasive procedure. However, patient choice, particularly in functional surgery, is paramount and this, combined with concerns over mesh complications and the Montgomery ruling[10] suggests patients should be informed of all suitable options.

These data show that historically, in the UK patients undergoing PUB were older than those

Table 3. Postoperative complications (no concomitant surgery).

	Bulking	RPT	*p* value
Return to theatre <72 h	0.17%	0.61%	ns
Catheterisation >10 days postop	0.87%	3.29%	0.001
Return to hospital <30 days for procedure related event	2.73%	8.07%	0.01
Readmitted to hospital <30 days for procedure related event	0.91%	4.30%	<0.01

Note: 'Unanswered' were not included in this analysis.

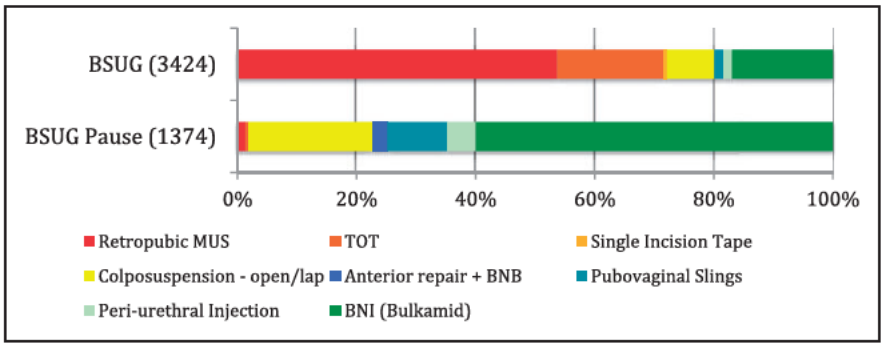


Figure 8. BSUG trends pre (2017) and post pause (1 August 2018 to 31 January 2019).
Note: Please refer to the online version of the article to view the figures in colour.

undergoing RPT, which probably reflects previous preferences of offering PUB to elderly medically unfit patients. This has changed now following the mesh pause in the UK.

The most common UDS, as expected, is USI for both procedures but for PUB there are a smaller percentage of patients that had pure USI. This may be because clinicians favour their use if the diagnosis is more complex to aim for improvement in symptoms without the risks of the larger SUI operations.

It can be difficult to compare these data to other studies as there are many different outcome measures. Success rates of 59.2% for PUB and 91% with RPT with respect to PGI-I and 28% for PUB and 77.6% with RPT for cure of SUI are seen in this cohort of patients from the BSUG database. The Cochrane review found a range of 71%–97%[3] for subjective cure rates in the first year, so reassuringly the British Urogynaecologists have appropriate results with tapes but the results with PUB are lower than the range of 66%–89% found in the systematic review.[2] The lower success rates may be due to surgical experience as many centres were low volume users and this has been shown to give poorer outcomes in gynaecological surgery[11] and specifically in PUB on analysis of the Danish database 'DugaBase'.[12] It is not possible to compare the results of this study with the ongoing TVT versus Bulkamid study as the outcome measures are different. There are also differences in the techniques as those patients were operated on with local anaesthetic but on the BSUG database only 30.3% of patients had local anaesthetic for PUB (33 unanswered) and 13.9% for RPT.[5]

To eliminate the difficulty of comparisons between studies a core set of outcome measures for each condition should be considered to allow follow-up and international comparison of routine clinical care as developed by ICHOM for OAB.[13]

There are inherent difficulties using patient reported outcome measures as an outcome as 'success' is partially dependent on the counselling prior to the procedure. If the patient is told to expect complete cure then anything else will be a 'failure'; however, if the patient expects improvement, then they will count this a 'success'. This in itself demonstrates how important appropriate realistic counselling is and allowing the women to decide the best option for herself. It has been shown that if counselled fully patients are more likely to opt for the least invasive treatment[14] and it is important that women are given the options and for clinicians to be aware of the patients' expectations.[15] Counselling can be more directed if surgeons use their own data and the database is set up to allow results to be shown to patients in clinic as part of the counselling process.

Strengths and weaknesses

Large datasets are useful in providing insight into clinical practice with real life outcomes, and contribution should be encouraged. The inclusive nature of national databases can give patients more relevant information compared to strictly controlled RCTs which may include highly selected cases performed by experienced surgeons. The downside of this is that the group is very heterogeneous but with careful database development subgroup analysis can be performed.

This is a pragmatic study that gives insight into current practice and gives outcome for real life situations however there was a high volume of missing outcome data. This is not an uncommon limitation in database research. Whole centres, individual clinicians or individual patients may be missing from the database due to clinician oversight or intention to exclude some or all data. There is also the assumption that complications have been accurately recorded on the database but if the patient did not present to the index hospital the complication may be missed. Follow-up time scale was variable and short term and the consideration of longer term follow-up via phone app, email or other method should be considered. This database is limited to surgical in comparison to the American Pelvic Floor Disorders Research Registry which includes conservative management strategies such as pessaries.[16]

With respect to patient counselling it is important to inform patients of the lower success rates with PUB but this may be acceptable to the patient in view of the lower rates of complications.

The data presented in this paper are important as it gives 'real life' success and complications in a large cohort of patients treated by a broad spectrum of clinicians which complements information from RCT. If clinicians are maintaining their own data, then they will be able to compare their results with the national results and inform patients of their personal outcomes.

With more analysis like this, we will hopefully be able to risk assess patients who are more likely to be successful with PUB and therefore can be more fully counselled.

Précis

Analysis of 1386 bulking agents from a national database shows real life success rates of 59% with no intraoperative complications and should be a universal option.

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Ethical approval

Ethical approval for this study was not required, because individual centres using the database are required to be com pliant with UK Caldicott Guardian (data protection) regula tions. Patients give consent to their anonymised data being used for analysis.

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